Nevedal, Kristin@Cannabis

From: Marco Troiani <marco@digammaconsulting.com>
Sent: Wednesday, November 20, 2024 5:08 PM
To: cac@Cannabis
Cc: Marc Whitlow; Debby Goldberry
Subject: Public Comment for 11/21 CAC Meeting
Attachments: 20240813_scope_services_audits.pdf; Cannabinoid_DB_20241011.pdf; Audit_Edibles_20180824.pdf; DigammaSA20170403.pdf; Digamma Self Audit.pdf; MTF Pesticides Audit Checklist Rev 8 - June 2023.pdf; MTF Potency Audit Checklist Rev 7 - June 2023.pdf; MTF General Audit Checklist Rev 12.0 - June 2023.pdf

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Hello CAC Team,

I am writing to submit our public comments on the issues relating to the cannabis industry, particularly the following:

1. **20240813_scope_services_audits.pdf** - A scope of services for specialized audits that focus on cannabis analysis, with an emphasis on cannabinoid inflation and pesticide and mold suppression.

2. **Cannabinoid_DB_20241011.pdf** - A draft of the collaborative project of all known cannabinoids. This resource is very helpful to regulators and other interested parties in understanding the chemistry behind cannabis and hemp clearly and authoritatively.

3. **Digamma Self Audit.pdf**
4. **DigammaSA20170403.pdf**
5. **Audit_Edibles_20180824.pdf** - These 3 forms are examples of freely available self-audits for cannabis testing laboratories. They focus on general lab practice, pesticides, and edibles, which are 3 difficult areas in the testing sector of the industry. These are generated by Digamma.

6. **MTF General Audit Checklist Rev 12.0 -June 2023.pdf**
7. **MTF Pesticides Audit Checklist Rev 8 - June 2023.pdf**
8. **MTF Potency Audit Checklist Rev 7 - June 2023.pdf** - These 3 forms are examples of freely available audits for cannabis testing laboratories from Colorado's Department of Public Health. They focus on general lab practice, pesticides, and cannabinoids, which are 3 difficult areas in the testing sector of the industry. These are generated by CDPH of the state of Colorado. We believe Calfiornia will need a more through scope, like that outlined in item 1 "**20240813_scope_services_audits.pdf**" to be effective in achieving its currently stated goals in cannabis regulation.

Please Note: We have previously on September 18th (09/18) sent materials outlining the problems of cannabis analysis and hemp laws from a more reference and educational perspective. As these documents are long and substantive, we realize not all committee members may have had time to review them all. But as they are still very helpful in grapsing the scope of nature of the problems the committee is attempting to address, we have included a PostScript below which summarizes all of those documents as well. If any member of the committee or staff at the DCC would like a copy of any of these we would be more than happy to provide them.

Please let us know if you need anything else from us or if there is anything we can help clarify.

Cheers,

Marco Troiani
CEO & Co-Founder
Digamma Consulting
marco@digammaconsulting.com

P.S.

Hello CAC Team,

I am writing to submit our public comments on the issues relating to the cannabis industry, particularly the following:

1. Cannabis lab fraud and cannabis inflation. Filename: **20240313_Cannabinoid_Inflation_Whitepaper.pdf**

2. Federal Recreational Hemp phenomenon competing without taxes or safety testing. Filename: **The-federal-recreational-hemp-phenomenon.pdf**

3. Synthetic d9-THC derived from hemp adulterating state-licensed cannabis products and testing to prevent this adulteration: Filename: **20240918_hemp_adulteration_proposal.pdf**

Please let us know if you need anything else from us or if there is anything we can help clarify.

Cheers,

Marco Troiani
CEO & Co-Founder
Digamma Consulting
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SCOPE OF SERVICES

Regulatory Agencies

***Note**: This is a scope of services document, not a proposal for a specific project. If you would like Digamma to generate a custom proposal for your project, please send a request to admin@digammaconsulting.com, and someone will follow up shortly.*

Thank you for your interest in Digamma Consulting's analytical laboratory audit solutions. Developing a comprehensive laboratory audit protocol is essential to ensure uniform auditing standards across laboratories. Laboratory audits often involve overlapping assessments, such as the prescriptive AOAC evaluation, which intersects with the ISO 17025:2017 assessment, and audits conducted by local and state regulatory authorities—particularly relevant for cannabis labs.

These laboratory audits can be performed either by state regulatory staff trained by Digamma Consulting or outsourced directly to our team of experts. It is also crucial to differentiate between using these audit protocols to regulate licensed third-party labs and enhancing the legal defensibility and precedent for data produced by a state-owned reference laboratory.

Digamma Consulting offers a range of audits tailored to assess the chemical analysis conducted by cannabis testing laboratories, ensuring the scientific accuracy and legal defensibility of the data generated. This service is invaluable for regulators, accreditors, inspectors, and any organization closely associated with cannabis testing labs, where verifying process accuracy and data integrity is paramount.

If you are interested in exploring Digamma's services, please contact us at your convenience, and we will schedule a time that suits you. We look forward to the opportunity to collaborate and assist in the growth of your organization.

Sincerely,

Marco Troiani
CEO
Digamma Consulting

Marc Whitlow
CFO
Digamma Consulting

APPENDIX A

CANNABIS LABORATORY CANNABINOID AUDITS

Executive Summary: Digamma Consulting uses a rigorous 10-step audit approach tailored for state regulatory agencies to ensure lab compliance. Each step is carefully crafted to guarantee accurate and reliable cannabis lab results, upholding the integrity of cannabinoid content reporting.

Outline of a Cannabinoid Analysis Laboratory Audit Steps

- Calibration / Reference Standard Manipulation
- Calibration Curve Manipulation
- Sampling
- Sampling Size, Homogenization, and Replication
- Correction Factors - Mass
- Correction Factors - Decarboxylation
- Chromatographic Co-Elution
- Detector Manipulation
- Data Analysis Manipulation
- Physical Instrument Parameter Manipulation

Digamma Consulting has identified critical components involved in the practice of cannabinoid inflation within the industry. These essential elements should be integrated into any audit protocol investigating this issue in suspected laboratories. Organized into specific categories, Digamma has precisely outlined the practices to be examined during an audit. The audit findings will be compiled into a comprehensive report for state regulatory agencies, providing detailed insights into the observed practices.

Calibration / Reference Standard Manipulation

Audit Deliverable Purpose: To investigate the manipulation of calibration standards through degradation, improper dilution, and sourcing of less-than-reputable concentration standards.

Recommended Audit Actions:

- Audit calibration standard storage and handling procedures to ensure a lack of degradation.
- Audit the calibration curve standard preparation from the stock material purchased by the lab.
- Review sources of calibration standards and their reliability for use as reference standards.
- Analyze unopened, stored, and diluted calibration standards for quantitative comparison of concentrations used by the laboratory (done by the lab's equipment or the state reference lab).

Note: ISO/IEC 17025:2017 already requires the use of accredited CRM when possible and requires verifications. However, the laboratory's internally developed method

determines the acceptance criteria (related to continued use after opening or expiry). Therefore, they could be a source of manipulation and should be prescribed by a regulator.

Calibration Curve Manipulation

Audit Deliverable Purpose: To investigate manipulations of calibration curves through extrapolated calibration curves, improper dilution steps in sample prep, and manipulations of the calibration curve.

Recommended Audit Actions:

- Audit of the procedure for quantifying unknown samples using Linear Dynamic Range (LDR), derivation of LDR, calibration curve standard concentrations, and LOQ and LOD values.
- Review and assess the matrix recovery values for compliance with accuracy and precision requirements.
- Audit the sample prep process to evaluate extraction efficiency, dilution procedure, and compliance with the method's declared LDR.

Sampling

Audit Deliverable Purpose: To investigate sampling procedure, including biased sampling of the batch or the laboratory representative sample, mis-weighing or mis-volume in sample prep steps, or contamination of samples during prep.

Recommended Audit Actions:

- Audit of procedure governing sampling of batches. *Note: This is examined in further detail in the next section on "Sampling Size, Homogenization, and Replication."*
- Audit the procedure governing the storage of samples.
- Audit the procedure governing the transportation of samples.
- Audit the procedure governing sub-sampling batch samples within the laboratory for individual analysis of each instrument. *Note: This is examined in further detail in the next section on "Sampling Size, Homogenization, and Replication."*
- Audit procedures governing sample weighing, scale calibration, and verification.
- Audit procedures governing pipette use, calibration, and verification.
- Audit procedures governing inventory record keeping.
- Audit procedures governing cross-contamination and adulteration prevention policies and practices.

Note: Calibration under ISO 17025:2017 for pipette balance 'inventory' is required. However, acceptance criteria for ongoing use & calibration schedule determined by the laboratory are outside the 'ISO/IEC 17025:2017 clause,' which would address an audit of product inventory.

Sampling Size, Homogenization, and Replication

Audit Deliverable Purpose: To investigate biased sub-sampling sizes using replicates in a method that allows for reporting of the highest observed value and any homogenization practice that would manipulate the final reported result, including contamination with target compounds.

Recommended Audit Actions:

- Audit of procedures outlining homogenization and sub-sampling of representative

samples of the production batch performed in the analytical laboratory, including examining the following items:
    - Sub-sampling mass size,
    - Replicate analysis policy and practices and their effect on reporting, and
    - Homogenization procedure used in the laboratory.
- Audit of the sampling size and its impact on replicate testing on the same batch of material indicates precision and repeatability, including standard deviation (STDev); significant variance combined with a policy of replicate testing by selecting a single or sub-section of results can easily give a higher-than-average value.

Note: Many laboratories do not consider the loss of volatiles such as terpenes and other VOCs statistically significant when reporting moisture in plant samples. Digamma's reviewed statistical data supports this claim, and the calculations supporting it can be verified for each audited laboratory.

Correction Factors - Mass

Audit Deliverable Purpose: To investigate the manipulation of mass-based correction factors, such as stem removal and moisture, and ensure that all correction factors are used accurately and uniformly and are not a source of errors or manipulation of reported results.

Recommended Audit Actions:

- Audit sample preparation and reporting procedures, focusing on the selective removal of plant tissue, such as stems.
- Examine correction factors for moisture content by mass, as inaccurate moisture values can manipulate cannabinoid results.
- Address issues with excessive heating of samples, which can lead to inflated moisture and cannabinoid content values after dry-weight correction.
- Investigate the moisture content procedure thoroughly, including auditing the process and reviewing all related quality and validation data.

Correction Factors - Decarboxylation

Audit Deliverable Purpose: To investigate improper use of molecular mass conversions, such as those between THCA and THC and other cannabinoids and their corresponding acid forms. It would also review the manipulation of reported results by improper summation of values such as unrelated or antagonistic cannabinoids such as THC and CBD.

Recommended Audit Actions:

- Evaluate the accuracy of correction factors, such as those used for cannabinoid acid decarboxylation.
- Assess the validity of reported equivalent concentrations post-conversion, including Total THC, CBD, and other compounds derived from theoretical calculations.
- Investigate claims of Total Active Cannabinoids (TAC), Total Potential Cannabinoids (TPC), and other potentially misleading statements on laboratory labels that lack supporting scientific evidence.

Note: To thoroughly assess these conversion factors, the precise mass conversion factors must be derived from regulatory guidelines or scientific literature, and the

policies regarding the reporting of combined, total, or potential cannabinoid concentrations must be carefully reviewed.

Chromatographic Co-Elution

Audit Deliverable Purpose: To investigate the mis-integration of non-target compounds by the analytical method, including other cannabinoids and UV-active compounds like waxes common in the cannabis plant. It includes intentional allowance of target compound carry-over from one sample analysis to the next in the same instrument, which inflates the final reported value relative to the amount present in the sample. Laboratories employing very short columns enable co-eluting compounds to artificially increase their reported values in matrix samples. This manipulation does not impact solvent standard calibrations, yielding compliant quality control sample data and Proficiency Testing (PT) results in some instances.

Recommended Audit Actions:

- Conduct an audit of chromatograms for target compounds to assess potential co-elution of other targets or matrix interferences that may affect the measured quantity of the target compound.
- Reviewing chromatogram procedures will be compared to the declared values and procedures outlined in the method's validation report.
- Assess the column length and maximum resolution. This issue can be examined by scrutinizing the data declared in the validation report on matrix interference studies and conducting an audit of routine quality samples that pertain to these components, including matrix blanks (MB) and matrix spike replicates (MSRs).
- Evaluate the instrument flush time and address carry-over contamination through solvent blanks, prep blanks, calibration blanks, and similar QC data points.
- Conduct a comprehensive matrix interference assessment, including a list of known interferences for a tested sample matrix.

Detector Manipulation

Audit Deliverable Purpose: To investigate the manipulation of detector settings, which may allow interfering compounds to be mis-integrated as target compounds.

Recommended Audit Actions:

- Audit instrument UV or visible light frequency used by the detector.
- Audit instrument the quantitation versus qualifier detector channels.
- Audit instrument any qualifying channel ratios derived from analytical standards.
- The audit will focus on known interferences declared in the analytical method's validation report and the probability of these interferences having a substantive impact on the final reported result of the target compound.

Data Analysis Manipulation

Audit Deliverable Purpose: To investigate the manipulation of data analysis procedure, emphasizing the mis-integration of target compounds, mis-integration, and manipulation of calibration standard integration.

Recommended Audit Actions:

- Conduct an audit of instrument chromatogram integration procedures, policies, and practices involving a comprehensive review of all manually integrated peaks from a randomly selected analytical batch conducted by the laboratory.

- The investigation will collect data on the amount and frequency of manual integrations versus auto-integrations per analytical batch for baseline consistency from peak to peak and the relationship of integration technique between calibration, quality, and client samples.
- The audit will focus on Gaussian integration parameters, including the following:
  - Auto-integration v. manual,
  - Baseline integration of noise,
  - Baseline up-shifting of integration area lowering final value (for LQC rather than direct inflation on client samples), and
  - Retention time variation and manipulation.

Physical Instrument Parameter Manipulation

Audit Deliverable Purpose: Investigate alterations in physical parameters on the analytical instrument by tracking logs to detect inconsistencies with the method's validation report and Proficiency Testing (PT) rounds. This includes identifying signs of manipulation, missing data, or alterations coinciding with periods of high reported values.

Recommended Audit Actions:

- Audit all instrument logs that verify the invariance of physical variable settings that impact the final reported value, including:
  - Injector volumes,
  - Flow rates,
  - Temperature settings,
  - Vacuum pressure,
  - Electrovoltaic parameters, and
  - Electromagnetic parameters (mass spec methodologies only).
- Traceability practices that show the physical parameters of the analytical method printed into each data packet by each analytical batch would make a step of the audit performable with document and data review only.
- If the laboratory in question does not adhere to standard traceability practices, on-site audits of current and established procedures will be essential to validate the uniformity of these physical instrument parameters.

APPENDIX B

CANNABIS LABORATORY PESTICIDE AUDIT

Executive Summary: Digamma offers a comprehensive audit protocol for pesticide analysis in cannabis laboratories, highlighting critical stages of analyte selection, matrix considerations, homogenization, extraction, and data integrity. Each step is meticulously detailed to ensure laboratory practices' accuracy, reliability, and defensibility, providing essential guidance for auditors in detecting and preventing inaccuracies or potential manipulations.

Outline of a Pesticide Analysis Laboratory Audit

- Analytes
- Matrix
- Homogenization
- Extraction
- Analysis
- Data

Digamma has provided insights into key components utilized in the pesticide analysis practiced in the industry. These crucial elements should be incorporated into any audit protocol designed to investigate this phenomenon in laboratories. These components have been organized into specific topics, and Digamma has concisely described the practices to be scrutinized during an audit. The resulting information will contribute to an audit report delivered to the state, presenting comprehensive findings on the observed practices.

Analytes

Audit Deliverable Purpose: To investigate the appropriate alignment of each analyte with the proper detection technique. This includes alignment with instrument components such as ionization sources, which are analyte-specific, as well as storage, solvent, and extraction conditions of said pesticide analytes.

Recommended Audit Actions:

- Audit the list of analytes on the analytical method and align with the proper detection technique, particularly with tandem mass spec (MS/MS) alignment of each analyte with a viable ionization source, which is particularly important to the accuracy of generated data.
- Review each analyte's storage conditions and solvent usage, including polarity, stability, pH, and cross-reactivity with other analytes.
- Review sources of calibration standards and their reliability for use as reference standards.
- Analyze unopened, stored, and diluted calibration standards for quantitative comparison of concentrations used by the laboratory (this can be done by the lab’s equipment or the state reference lab). Focus on the expiry management system for preparing pesticide solutions and managing their stability.

Matrix

Audit Deliverable Purpose: Across all matrices, four major interferences are typically observed: cannabinoids and terpenes, waxes and lipids, carbohydrates and amino acids, and polymers. Because each matrix class has varying ratios of the interfering compounds, matrix-matching the calibration is necessary to ensure consistent recoveries. This section examines the appropriateness of matrix choices in the methodology and their impact on reported data's accuracy.

Recommended Audit Actions:

- Assess the number and composition of the matrix classes that the analytical method used by the laboratory organizes for all received cannabis samples across all types. Key chemical components to monitor are:
  - Cannabinoids,
  - Terpenoids,
  - Waxes and other plant lipids,
  - Carbohydrates (simple and complex),
  - Amino acids and protein. and
  - Synthetic polymers and emulsifiers.
- Assess the appropriateness of matrix blank and other matrix sample proxies used in the method to sample type by examining the chemical composition of proxies and client samples.
- If matrix-matched calibration is used, the accuracy and precision of matrix-calibrated values must be assessed when compared to the same values in the solvent standard.
- If internal standard correction factors are used, the accuracy and precision of the corrected values in the matrix compared to corrected values in the solvent standard must be assessed.

Homogenization

Audit Deliverable Purpose: Proper homogenization of each sample tested is required for reproducibility of reported data. Pesticide distribution is often not uniform, so samples should be homogenized to fine particle sizes and well-mixed. A fine particle mesh also allows less acetonitrile to be sequestered in the plant matrix and a greater volume of acetonitrile to be collected after sample extraction.

Recommended Audit Actions:

- The homogenization technique's precision, accuracy, and repeatability were demonstrated through matrix spike replicates, either through validation data or with a CRM using the lab's method.
- Volume extraction recovery data showing inputted and recovered extraction volume from the homogenized sample matrix. If correction factors such as matrix-matched calibration or internal standard calibration, correction factors must be assessed for accuracy of recovered volume and analyte.

Extraction

Audit Deliverable Purpose: LC and GC systems have different vulnerabilities regarding matrix interferences and require extraction clean-up approaches that protect each instrument and allow for accurate and precise analyte quantitation. Extraction procedures must be validated for final recoveries, and any interactions with correction

factors (matrix-matched or internal standard) must be verified quantitatively.
Recommended Audit Actions:

- Review the appropriateness of the clean-up procedure for each analyte assigned to each instrument (see **Analytes** section above).
  - Major analyte loss at a theoretical chemistry level can be detected from these reviews (daminozide, captan, etc.) by cross-referencing chemical polarity with clean-up extraction procedures applied to each analyte at each instrument.
  - Major analyte loss theoretically predicted can be verified with existing laboratory records or low-resource additional analysis if it is already present.
- Review data logs to verify instrument sensitivity stability with analytes over time with extraction and clean-up recovery values to disprove an instrument drift or cumulative analyte loss in extraction efficiency.
- Review data logs to verify instrument sensitivity stability with interferences over time with extraction and clean-up recovery values to disprove an instrument drift or analyte accumulation in extraction. Ideal interferences to monitor cannabis products include:
  - THC,
  - CBD,
  - CBG, and
  - Plant cuticle waxes.
- Recoveries after clean-up must be assessed for repeatability in final reported values as measured by the following:
  - Relative Percent Difference (RPD),
  - Standard Deviation (STDev), and
  - Mean Accuracy ($\%R_{avg}$).

Analysis

Audit Deliverable Purpose: The analysis phase involves critical areas where errors or manipulations can occur, such as autosampler and inlet conditions, affecting accuracy in liquid (LC) and gas chromatography (GC). Thorough rinsing of the GC sampling needle is necessary to prevent jams, and matrix-matched or internal standard-corrected calibration curves are required to address hidden influences on instrument response. High-quality LC/MS-grade solvents are essential to avoid contamination, and additional chromatographic separation may be needed for each matrix class to ensure selectivity and accuracy.
Recommended Audit Actions:
Autosampler Section

- Review autosampler and inlet temperature for compatibility with analyte stability.
- Review of the rinse programs used by the instrument to ensure that there is no possibility of residue or degradation of analytical equipment.
- Replicate analysis data review to verify the lack of signal drift in the detector, accumulation, and decay.
- Needle dwell and fill times for each instrument and review of appropriate and repeatable instrument processes. An emphasis on the following points is recommended:
  - Oxidative loss of analyte in high-temperature environments/dwell times.
  - Un-repeatable fill volumes of LC loops or GC needles cause high

deviations.

Chromatography Section

- Review solvent standard instrument responses and matrix spike instrument responses to disprove the presence of dark interferences in the matrix for the method.
- Review the retention time of analytes in both solvent standard and matrix to disprove matrix shifts.
  - Review both deviation and mean accuracy of retention time for each analyte.

Mass Spectrometry Section

- Mass channel selectivity review based on responses in standard and matrix.
- Review adduct and fragment calculations to verify that signal responses authentically indicate the analyte's concentration.
  - Theory: Use molecular mass calculations.
  - Practice: Compare data sets, such as standard addition or matrix-matched calibration, to validate results.s such as standard addition or matrix-matched calibration
- Review signal-to-noise values in solvent standard and matrix to verify the method's stated LOD and LOQ values from validation.
- Review of isotopic channels, which help to validate signal-to-analyte association by revealing the presence of characteristic and sometimes unique atoms.
  - Theory: Based on the analyte's formula, calculate isotopic abundances at the A+1 and A+2 mass channels. Note: Errors here may necessitate changes in fundamental method development.
  - Practice: To confirm theoretical calculations, measure A+1 and A+2 mass channel relative abundance in solvent standards and matrix samples.

Data

Audit Deliverable Purpose: Data defensibility is the most critical part of any chemical analysis and is the underlying architecture of both a compliant method validation and a thorough laboratory audit. The validation metrics are verified by daily Quality Control (QC) samples whose data is kept in the QC log for records. These are outlined below by QC samples designed to measure and demonstrate their presence or absence in the data a method generates.

Recommended Audit Actions:

- Review QC logs for routine compliance with validation, accreditation, and licensing criteria.
  - Linearity as measured by:
    - Correlation coefficient (R^2 value),
    - Linear Dynamic Range (LDR), and
    - Calibration point residuals.
  - Precision as measured by:
    - Matrix Duplicates (MD),
    - Sample Duplicates (SD), and
    - Continuing Calibration Verification (CCV).
  - Accuracy as measured by:
    - Matrix Sikes (MS),

        - Lab Control Standards (LCS),
        - Independent Calibration Verifications (ICV), and
        - Continuing Calibration Verification (CCV).
    - Range as measured by:
        - Method Reporting Limit (MRL),
        - Limit of Detection (LOD), and
        - Limit of Quantitation (LOQ).
- Evaluate the Proficiency Testing (PT) Program participation and review associated performance data.
- Examine Certified Reference Material (CRM) data, which may be included in validation reports.
- Review key limits, such as Limits of Detection (LOD), Limits of Quantitation (LOQ), Action Limits (AL), and relevant Reporting Limits (RL).
    - Theory: Calculate these limits for key analytes to confirm the method’s detection capability.
    - Practice: Validate the method's detection ability by applying these calculations to real-world sample data, ensuring consistency with theoretical expectations.

APPENDIX C

CANNABIS LABORATORY MICROBIAL AUDIT

Executive Summary: Digamma has developed a comprehensive audit protocol to identify and mitigate potential manipulations in microbial analysis within the cannabis industry. By examining key stages such as sampling, extraction, analysis, and data handling, this protocol equips auditors with the necessary steps to uncover inaccuracies and ensure the integrity of laboratory microbial content reporting.

Outline of Microbial Analysis Laboratory Audit

- Sampling
- Extraction
- Analysis
- Data

Digamma has provided insights into key components utilized in the industry's microbial suppression practice. This practice is motivated by financial incentives driven by losses incurred when a batch fails a microbial test. These crucial elements should be incorporated into any audit protocol to investigate this phenomenon in suspected laboratories. These components have been organized into specific topics, and Digamma has concisely described the practices to be scrutinized during an audit. The resulting information will contribute to an audit report delivered to the state, presenting comprehensive findings on the observed practices.

Sampling

Audit Deliverable Purpose: Sampling is a major point of potential error and manipulation in microbiology. Because microbiology measures living organisms, sterile handling, and storage techniques are critical to the laboratory's generation of accurate and defensible results.

Recommended Audit Actions:

- Verify the scale weight log to verify that the total mass of the material being tested is being properly weighed and included in the final calculations.
- Random repeatable sampling shows conformity within pre-defined criteria comparable to microbiological results in food.
- Review standard operating procedures (SOPs) to ensure that recursive replicates (testing-until-you-pass) practices are now allowed, and review laboratory practices to demonstrate they are not occurring in the laboratory.
- Analyze unopened, stored, and diluted calibration standards for quantitative comparison of concentrations used by the laboratory (this can be done by the lab’s equipment or the state reference lab).
- Sterile handling techniques will be reviewed in SOP and verified by on-site observations. This includes the following:
  - Sterile handling and not introducing contaminants from the environment.
  - Cross contamination and not introducing contaminants from one sample to another.

        - Proper sample storage and microbial load preservation.
            - Under excessive sterilizing conditions, the microbial load is reduced relative to the original batch sampled.
            - Under excessive growth conditions, the microbial load is increased relative to the original batch sampled.
    - Appropriate homogenization steps are taken to extract and remove all microbial content being analyzed thoroughly, without excessive homogenization, which releases either antibiotic or reaction inhibitor compounds, which would affect the reported results for plating and PCR quantitative techniques, respectively.

Extraction

Audit Deliverable Purpose: Extraction is a critical step for accurate quantitation or detection, as the microbial load in the extraction suspension is highly susceptible to modification, often more so than in the original sample. Any errors in homogenization or preparation can significantly skew the final reported results, making it essential to independently verify and optimize these processes to ensure the highest precision and reproducibility in the analytical method.

Recommended Audit Actions:

- The time-sensitive nature of the extraction work-up is due to the potential for microbial fission (cell division) in this analytical method's extract suspension.
    - Theory: Review SOP steps to ensure batch analysis is performed promptly to minimize impacts on reported results.
    - Practice: Observe and verify on-site that practices align with the SOP to ensure timely and accurate execution.
- Review of extraction solutions used to generate microbial suspension and rule out any effects that may alter the reported value.
    - Review of pH and saline buffering elements required for microbial analytes.
    - The presence of carbohydrates and amino acids could promote microbial growth and increase final reported values.
    - The presence of antibiotics or other inhibitory compounds could compromise data accuracy.
- Review of volumes and homogenization techniques used in SOP to verify even distribution of microbial load from sample into suspension.

Analysis

Audit Deliverable Purpose: The analytical technique used greatly impacts the final reported value of a method. Although many methods exist, and many that will be invented in the future can be applied successfully to this audit, the most popular choices are agarose growth plate enumeration and quantitative Polymerase Chain Reaction (qPCR). For this reason, we will reference these techniques explicitly in the text below, but these audit actions can be applied to any microbial analysis technique.

Recommended Audit Actions:

- Agarose Petri Dish Enumeration qualifications are outlined in the four items below:
    - Dilution correlation - The dilutions CFU will be correlated to show agreement across the serial dilution series. Residuals can be calculated in the same way as a traditional calibration curve.
    - Significant figure verification - Verification ensures that the SOP and related

calculations correctly determine the number of significant figures the microbial method can accurately report for each analyte.
        - Proper spreader sterilization—When preparing a petri dish for enumeration, the spreader bar is a major source of cross-contamination (creating false positives) and sterilization (creating false negatives). Reviewing SOP and observing practice on-site can eliminate both possibilities.
        - Incubation Verification - Error or manipulation can occur if the samples are not incubated for the correct amount of time. Paper or, preferably, digital logs verifying the incubation time of each batch can disprove this practice in a laboratory.
    - Polymerase Chain Reaction (PCR):
        - Enrichment time—If the samples are not enriched for the correct amount of time, error or manipulation can occur. Paper or, preferably, digital logs verifying the enrichment time of each batch can disprove this practice in a laboratory.
        - Polymerase Kit (incl. storage) - Proper storage conditions of protein machinery found in PCR kits are critical for them to function at the proper reaction rate as calibrated for the analytical method and to have the correct concentration in the reaction vessel. Improper storage or handling can adversely affect these proteins and the final reported result.
        - Dilution Scheme - The dilutions Cp will be correlated to show agreement across the serial dilution series. Residuals can be calculated in the same way as a traditional calibration curve.
        - qCp correlation equation - Review and verify the accuracy of the Cp correlation equation used by the PCR analysis to generate a final CFU/g concentration of the microbial load being analyzed. This can be theoretically validated mathematically and verified with real-world data from the laboratory.
        - Inhibitor profile (matrix-specific) - This should be either made available by the instrument, method, consumables, or other manufacturer, but if the laboratory is developing their PCR analysis in-house or from base components in their reaction mixture, they are responsible for generating a known set of reaction inhibitors found in the sample matrix in question and apply these insights into developing a method which can produce reproducible data.

Data

Audit Deliverable Purpose: Processing raw data generated in the analysis and produced in parallel with Quality Control (QC) Samples is critical to generating an accurate and reproducible final result. This section addresses QMS qualification, final reported value calculations, compliance with reporting, and action limits.
Recommended Audit Actions:

- Final concentration calculator verification - This should often be presented in the final validation report, but a reference to an independent CRM, which was measured by the final analytical method, can verify all calculations and provide greater accuracy of the method overall.
- Replicate analysis—Replicate analysis is important to derive precision data, such as Relative Percent Difference (RPD) and Standard Deviation (STDev). Depending on the number of replicates performed, replicates can be performed on a spiked sample or a CRM.

- Global client trends - Global trends in reported client data can show bias around important concentration values, such as action limits. When a normal distribution shows such signs of manipulation near a value with a financial incentive, it strongly indicates some selective bias. It is a possible cause of intentional manipulation and fraud. This data can be reviewed to predict the laboratory's selective bias and subsequent conclusions.
- Qualitative (P/A) - Similar requirements as above are quantitative, but the specifically quantitative criteria are being removed or replaced with an appropriate metric of data accuracy.

Edibles Laboratory Self-Audit Form

Assessment of Laboratory Data Quality

Laboratory	
Address	
License No.	
Date Received	
Date Completed	
Point of Contact	

Legend
MSDS = Material Safety Data Sheet PDA = Photo Diode Array, also called Diode Array Detector (DAD) MS = Mass Spectrometer CRS = Certified Reference Standards IRL = Instrument Reporting Limit QAQC = Quality Assurance / Quality Control PT = Proficiency Testing MRL = Matrix Reporting Limit

Chemical Storage and Handling

Question	**Compliant (Y/N)**	**Comment Section**
A chemical inventory list is available and updated annually.		
MSDSs are available in the laboratory (paper and/or electronic copies) and laboratory personnel know how to access the information.		
Personnel wear appropriate protective equipment.		
Spill kit and instructions are readily available and clearly posted for small spills.		
Documented procedure on the safe and proper handling of chemical materials to avoid laboratory or material contamination.		
Proper storage conditions in terms of temperature, humidity, and safety; Incompatible chemical materials stored separately.		

Analysis of Cannabinoids: Instrument Calibration Quality Control

Question	Compliant (Y/N)	Comment Section
Cannabinoid potency analysis performed by PDA, MS, or comparable detector. Please indicate in comment section.		
Instrument calibrated by a CRS from a certified vendor. Please indicate supplier in comments.		
CRS are stored properly in laboratory and secondary dilutions bear CRS expiration date.		
The laboratory makes available the IRL for the cannabinoid potency analysis. Please indicate in comment section.		
The laboratory makes available the R2 value of the calibration curve used in cannabinoid potency analysis. Please indicate in comment section.		
Calibration curves are re-run according to QAQC manual either every fixed period of time or when analysis percent recovery falls outside of pre-determined acceptance criteria. Please indicate which in comment section.		
Continuing calibration standards are run every 10 client samples to verify instrument calibration throughout analytical batch.		
Continuing calibration blanks are run every 10 client samples to verify a lack of instrument contamination throughout analytical batch.		
The laboratory maintains a current annual, quarterly, or other calibration QC report showing instrument precision over time for each analyte reported and makes this information available to clients upon request. Please indicate in comment section point of contact for client to request such information.		
The laboratory has participating in available PT programs and makes the results available to clients. Please indicate in comment section point of contact for client to request such information.		

Analysis of Cannabinoid: Matrix Quality Control

Question	Compliant (Y/N)	Comment Section
Cannabinoid extraction has been validated in a matrix blank spike recovery study or comparable study generating data defending the method by confirming extraction efficiency		
The laboratory makes the matrix-matched validation of extraction efficiency available to clients upon request. Please indicate in comment section point of contact for client to request such information.		
The laboratory performs a matrix-based QAQC program associated with each analytical batch to validate the extraction efficiency, and accurate quantification in matrix		
The laboratory makes the matrix-based QAQC sample results associated with a analytical batch containing a clients samples available to said client upon request. Please indicate in comment section point of contact for client to request such information.		
The laboratory tracks MRL samples as part of the matrix-based QAQC program to ensure accuracy of the method in matrix at or near the method reporting limit.		
The laboratory maintains a current annual, quarterly, or other matrix-based QC report showing precision in matrix over time for each analyte reported and makes this information available to clients upon request. Please indicate in comment section point of contact for client to request such information.		

Digamma Consulting

digammaconsulting.com

350 Cannabinoids

Database of Known Cannabinoids

Version 1.3

Rev: Oct 21 2024 - 2024-10-21

This document represents a database of all known cannabinoids in Digamma's molecule database, generating a total of **350 cannabinoids**. These compounds are organized by category, displayed in the table of contents but explained in both the glossary and categorization diagram. We have included database number, acronym, full-name as well as the molecular diagram, chemical formula, exact molecular mass, and CAS identification number for each compound.

NOTE: Use Hyperlinks in table below to jump to each section

The definitions used to place a cannabinoid in a given category are outlinedi n the glossary and category diagram below. As selective breeding of cannabis plants continues, it is possible for a compound previous considered Trace Natural to become a high concentration Natural compound, as happened between 2000 and 2010 with compound **THCV**.

It is also worth noting that many compounds that are natural at trace levels are also indicators of synthetic cannabinoid reactions (whether the product is natural or synthetic, both can be made synthetically). Examples of strong indicator compounds of a synthetic reaction that are listed under Trace Natural + Semi-Synthetic category include **d8-THC**, **iso-THC**, **exo-THC**, **abnormal CBD**, and **cis-d9-THC**. Compounds such as these are listed under this category because they are present at trace levels in natural plant material, but their presence at higher levels are indicative of a synthetic reaction often from a textbfCBD precursor or similar.

Unfortunately, it is not as simple as a binary between a natural and synthetic compound for cannabinoids at this time, although that definition could be strictly drawn at the boundary between Trace Natural + Semi-Synthetic and Semi-Synthetic in a classical sense of whether a molecule has been detected in nature. The additional categories are added to aid in the proper illustration of cannabinoid-specific issues. These may include but not be limited to synthetic production of natural products and semi-synthetic compounds synthesized from natural products.

Glossary of Defined Terms

For the purposes of this database these terms have the following definitions. This is particularly important when using the decision tree to organize a candidate cannabinoid for the database into the appropriate category.

1. **Cannabinoid** – A cannabinoid is any small organic molecule capable of interacting, either as an agonist, antagonist, inhibitor both reversible and irreversible, of either cannabinoid receptor, namely CB1 and CB2 receptors.
2. **Cannabis spp.** - Cannabis species plants are those of the Cannabis genus in the Cannabaceae family under the Rosales order in classical biological taxonomic nomenclature (Linnaeus). This category includes plants commonly called “marijuana”, Cannabis, hemp and includes the species specific epithets of C. sativa, C. indica, C. ruderalis and various unnamed hybrid breeds thereof.
3. **Enzyme** – An enzyme is a protein that acts as a biological catalyst by accelerating chemical reactions. Enzymes are encoded in an organisms genome (DNA) and therefore can be described as native to a given organism. Enzymes catalyze reactions from precursor chemicals called substrates to output chemicals called products.
4. **Human synthetic activity** – Human synthetic activity is defined as human directed chemical techniques and technologies used to modify a molecule to a new stable structure. This may include but is not limited to the use of reagents, catalysts, electrovoltaic potential, ultraviolet or any other frequency of radiant energy. These processes have the potential to create unintended products in side reactions that may be hazardous to human health. With respect to cannabinoids and the scope of this document, these processes have become increasingly common in the US Cannabis and Hemp industries since the 2018 Farm Bill and the economic incentives of that bill are largely responsible for the increase in this human activity.
5. **Hydrocarbon skeleton** – For the purposes of this document, the hydrocarbon skeleton refers to the carbon-carbon bonds that make up the backbone of a cannabinoid structure. Modifications outside of this, such as heteroatoms (O, N, F, Cl, etc) are not considered part of the hydrocarbon skeleton, but organic groups such as methyl, ethyl, etc or modifications that severe or remove pre-existing natural C-C bonds that are not seen in nature are considered hydrocarbon skeleton modifications. This definition is critical for the definition between Fully Synthetic and Semi-Synthetic categories.
6. **Metabolite** – For the purposes of this document, metabolite is defined to mean any organic small molecule made by human cytochrome family of enzymes (CYP class) from a cannabinoid as a starting substrate.
7. **Molecule** – A molecule is any collection of atoms stably bonded together in covalent bonds with a consistent spatial geometry, forming a unique chemical species that can be repeatably detected by analytical chemical techniques.
8. **Trace concentrations** - In analytical chemistry, trace elements have an average concentration of less than 100 parts per million or less than 100 micrograms per gram, as defined in the second edition of the IUPAC Compendium of Chemical.

Category Decision Tree Chart

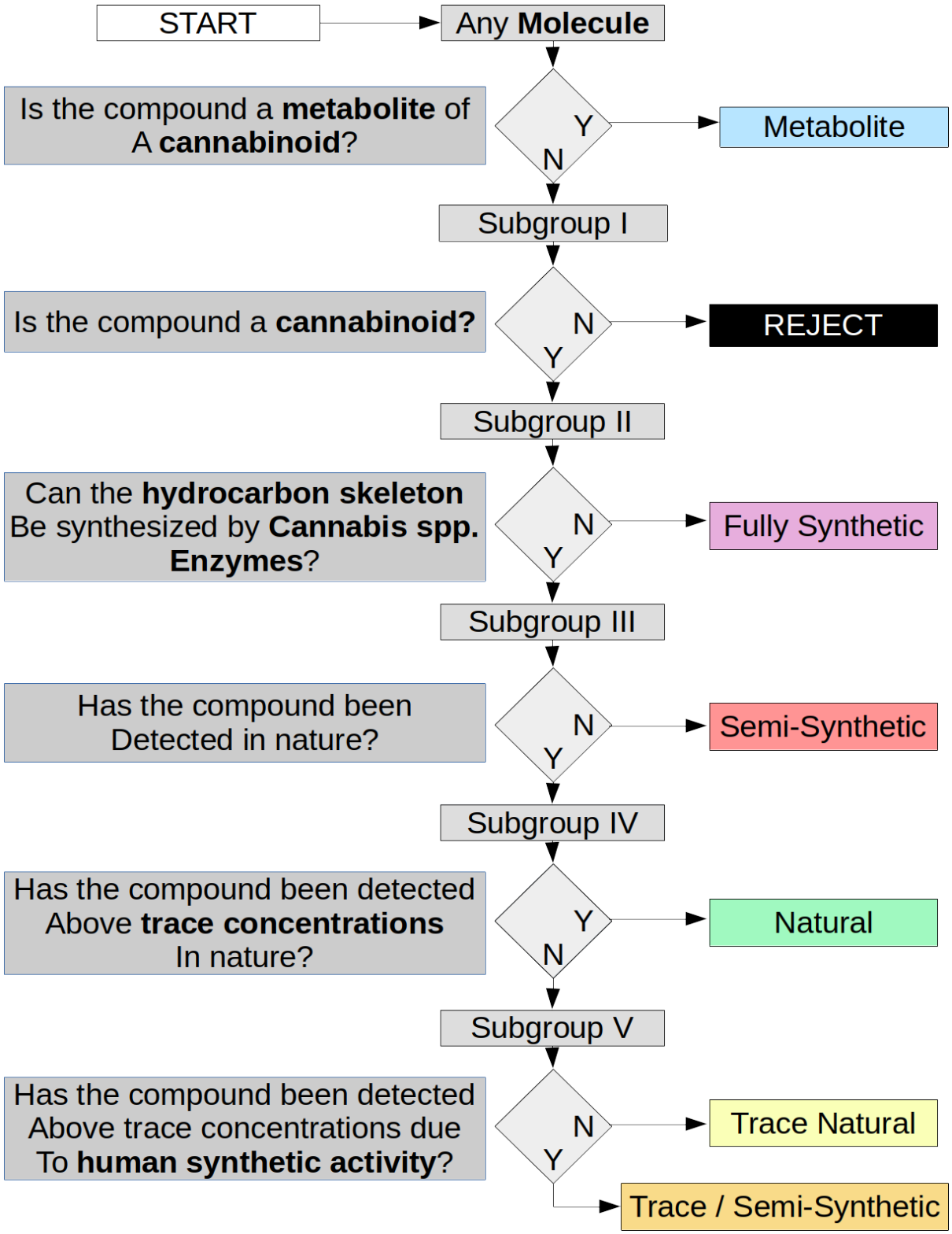


Table 1: Database of known Cannabinoids

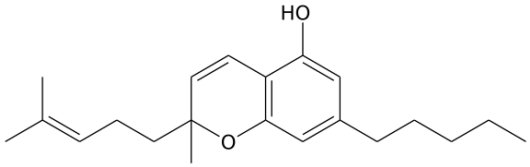
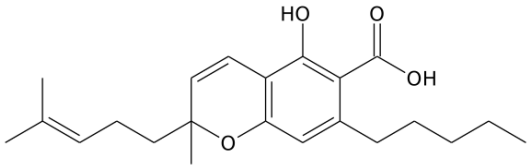
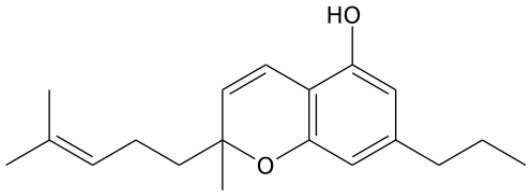
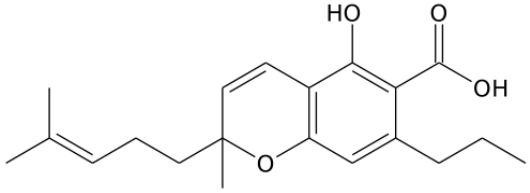
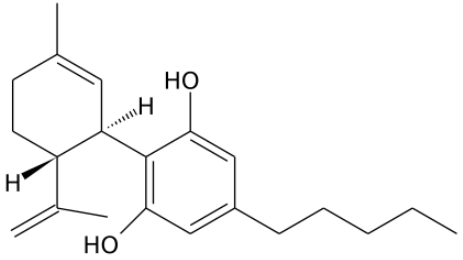
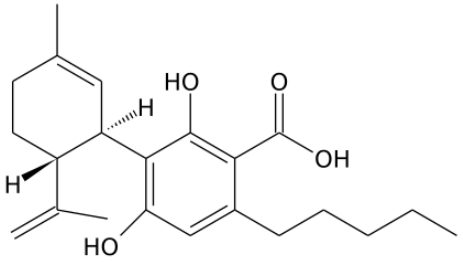
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10001	Natural	CBC	cannabichromene	$C_{21}H_{30}O_2$ 314.469 20675-51-8			
10002	Natural	CBCA	cannabichromenic acid	$C_{22}H_{30}O_4$ 358.478 20408-52-0			
10012	Natural	CBCV CBC-C3	cannabivarichromene Cannabichromene-C3 homologue	$C_{19}H_{26}O_2$ 286.415 57130-04-8			
10013	Natural	CBCVA CBCA-C3	cannabivarichromenic acid cannabichromene-C3 homologue	$C_{20}H_{26}O_4$ 330.183 1628112-69-5			
10003	Natural	CBD d1-CBD	cannabidiol Δ1-cannabidiol	$C_{21}H_{30}O_2$ 314.469 13956-29-1			
10004	Natural	CBDA d1-CBDA	Cannabidiolic acid Δ1-cannabidiolic acid	$C_{22}H_{30}O_4$ 358.478 1244-58-2			

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Table 1 – continued from previous page

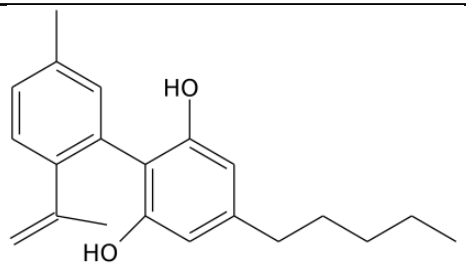
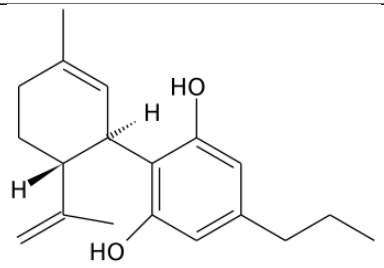
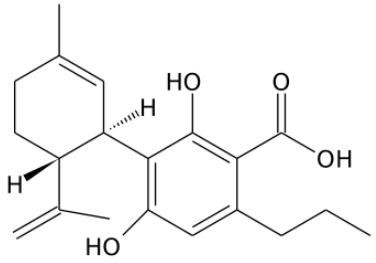
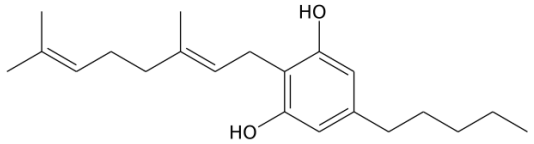
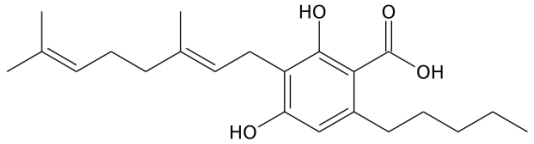
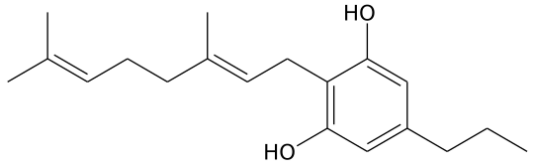
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10009	Natural	CBND	cannabinodiol	$C_{21}H_{26}O_2$ 310.437 39624-81-2			
10015	Natural	CBDV CBD-C3	cannbidivarin Cannabidiol-C3 homologue	$C_{19}H_{26}O_2$ 286.415 24274-48-4			
10231	Natural	CBDVA CBDA-C3	cannadivarinic acid cannabidiol-C3 homologue acid	$C_{20}H_{26}O_4$ 330.18309			
10005	Natural	CBG	cannabigerol	$C_{21}H_{32}O_2$ 316.485 25654-31-3			
10006	Natural	CBGA	cannabigerolic acid	$C_{22}H_{32}O_4$ 360.949 25555-57-1			
10007	Natural	CBGV CBG-C3	cannabigerovarin	$C_{19}H_{28}O_2$ 288.431 55824-11-8			

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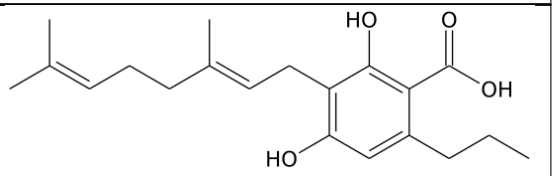
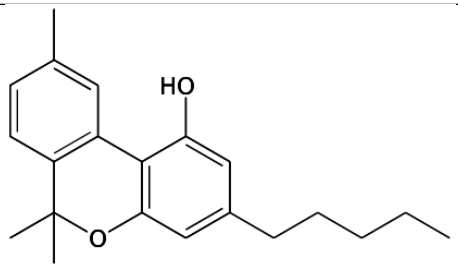
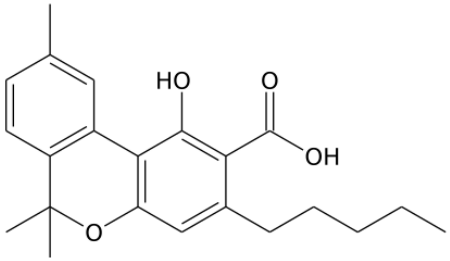
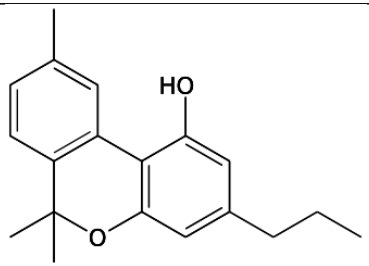
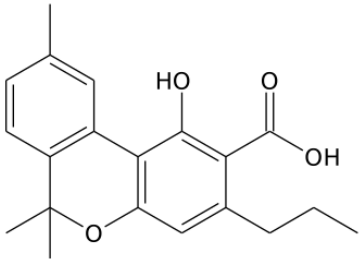
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10008	Natural	CBGVA CBGA-C3	cannabigerovarinic acid cannabigerol-C3 homologue acid	$C_{20}H_{28}O_4$ 332.2 64924-07-8			
10010	Natural	CBN	cannabinol	$C_{21}H_{26}O_2$ 310.437 521-35-7			
10011	Natural	CBNA	cannabinolic acid	$C_{22}H_{26}O_4$ 354.183 2808-39-1			
10014	Natural	CBNV CBN-C3	cannabivarin cannabinol-C3 homolgue	$C_{19}H_{22}O_2$ 282.38 33745-21-0			
10232	Natural	CNBVA CBNA-C3	cannabivarinic acid cannabinol-C3 homologue acid	$C_{20}H_{22}O_4$ 326.15179			

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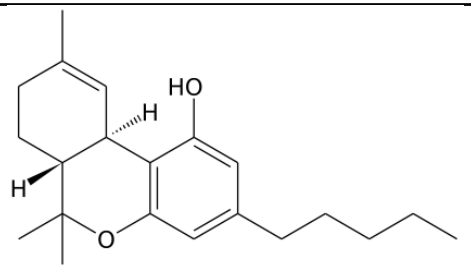
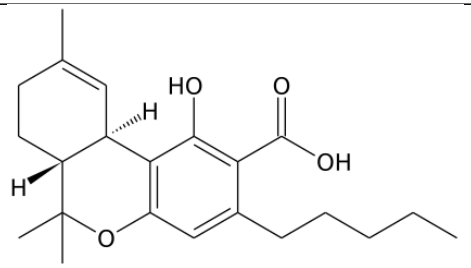
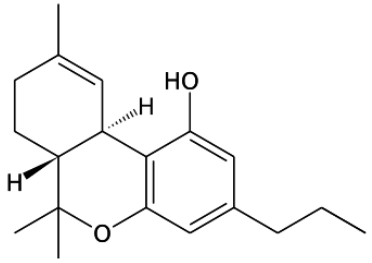
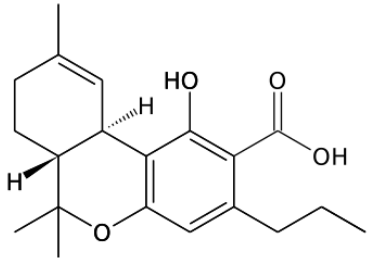
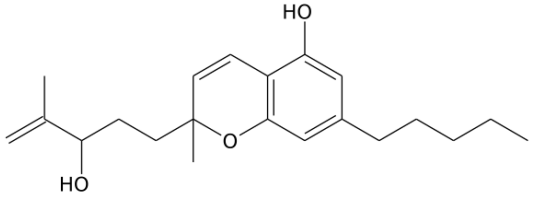
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10016	Natural	THC d9-THC (-)-trans-d9-THC (natrual entantiomer)	Tetrahydrocannabinol Δ9-tetrahydrocannabinol (-)-trans-Δ9-tetrahydrocannabinol (natrual entantiomer)	$C_{21}H_{30}O_2$ 314.469 26514			
10017	Natural	THCA d9-THCA	Δ9-tetrahydrocannabinolic acid-A	$C_{22}H_{30}O_4$ 358.478 23978-85-0			
10018	Natural	THCV d9-THCV THC-C3 d9-THC-C3	Δ9-tetrahydrocannabivarin Δ9-tetrahydrocannabinol-C3 homologue	$C_{19}H_{26}O_2$ 286.415 31262-37-0			
10019	Natural	THCVA d9-THCVA THCA-C3 d9-THCA-C3	Δ9-tetrahydrocannabivarinic acid Δ9-tetrahydrocannabinol-C3 homologue acid	$C_{20}H_{26}O_4$ 330.183 39986-26-0			
10024	Trace Natural	3”-OH-d4”-CBC	3”-hydroxy-Δ4”-cannabichromene	$C_{21}H_{30}O_3$ 330.464			

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Table 1 – continued from previous page

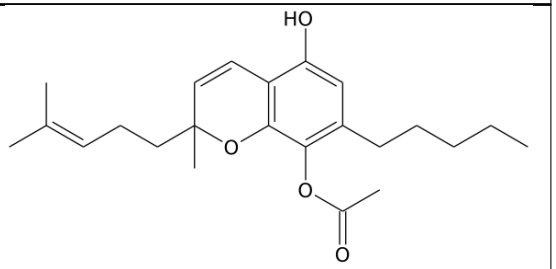
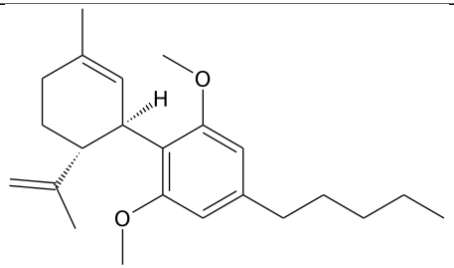
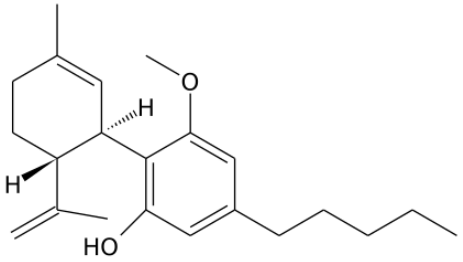
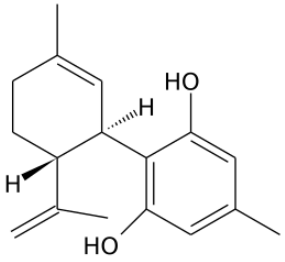
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10026	Trace Natural	4-acetoxy-CBC	4-acetoxycannabichromene	$C_{23}h_{32}O_4$ 372.501			
10042	Trace Natural	CBDD	cannabidiol dimethyl ether	$C_{23}H_{34}O_2$ 342.256 1242-67-7			
10043	Trace Natural	CBDM	cannabidiol methyl ether	$C_{22}H_{32}O_2$ 328.24 1242-67-7			
10044	Trace Natural	CBD-C1 CBDO	cannabidiol-C1 homologue Cannabidiorcol	$C_{17}H_{22}O_2$ 258.361 35482-50-9			

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Table 1 – continued from previous page

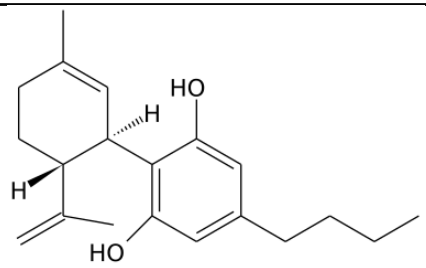
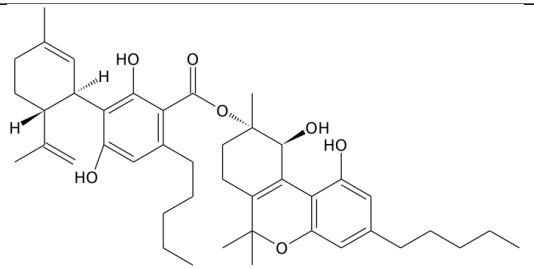
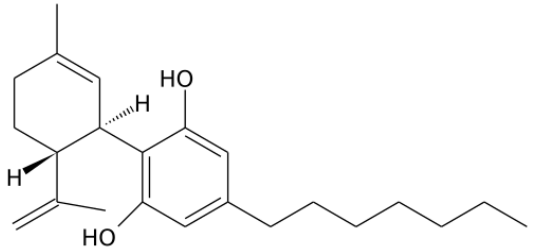
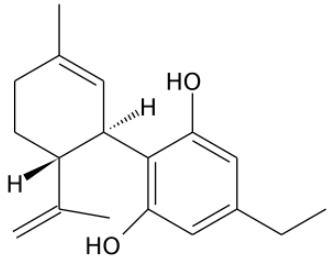
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10045	Trace Natural	CBD-C4 CBDB	cannabidiol-C4 homologue Cannabidibutol	$C_{20}H_{28}O_2$ 300.442 1972-05-0			
10046	Trace Natural	CBDA-9-O-CBT ester	cannabidiolic acid-9-O-cannabitriol ester	$C_{43}H_{58}O_7$ 686.924			
10047	Trace Natural	CBDP CBD-C7	cannabidiphorol cannabidiol-C7 homologue	$C_{23}H_{34}O_2$ 342.523 55824-13-0			
10169	Trace Natural	CBDE CBD-C2	cannabidiethol cannabidiol-C2 homologue	$C_{18}H_{24}O_2$ 272.4			

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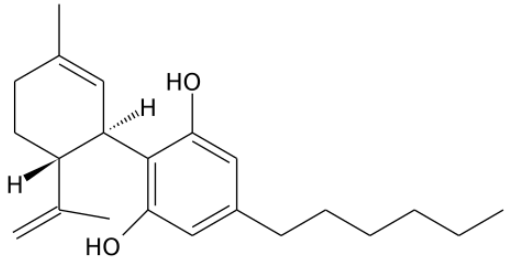
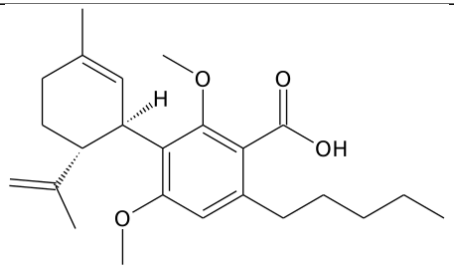
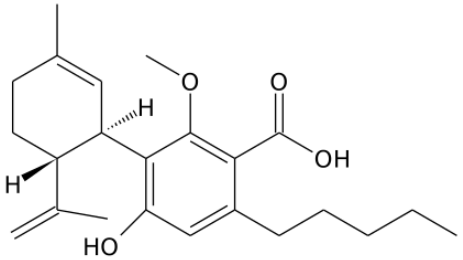
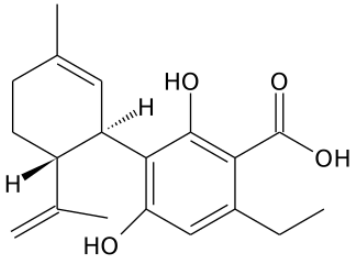
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10170	Trace Natural	CBDH CBD-C6	cannabidihexol cannabidiol-C6 homologue	$C_{22}H_{32}O_2$ 328.24022			
10184	Trace Natural	CBDDA	cannabidiol dimethyl ether acid	$C_{24}H_{34}O_4$ 386.24569			
10185	Trace Natural	CBDMA	cannabidiol methyl ether acid	$C_{23}H_{32}O_4$ 372.23004			
10208	Trace Natural	CBDEA CBDA-C2	cannabidietholic acid cannabidiol-C2 homologue acid	$C_{19}H_{24}O_4$ 316.16744			

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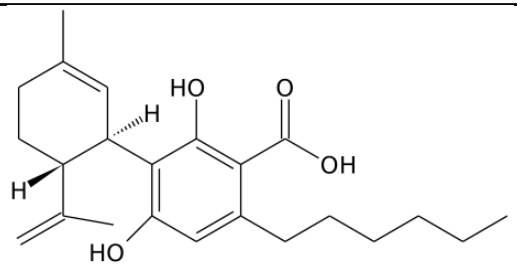
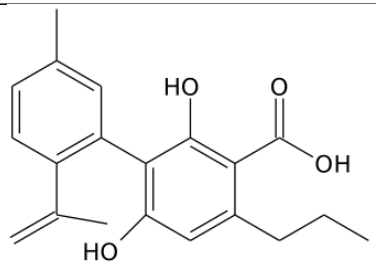
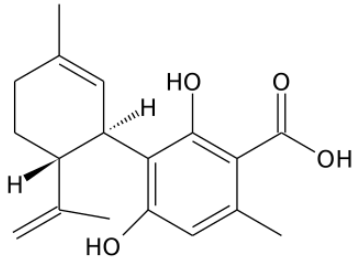
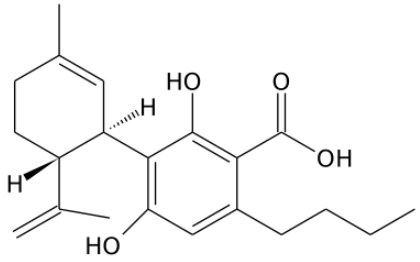
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10209	Trace Natural	CBDHA CBDA-C6	cannabidihexolic acid cannabidiol-C6 homologue acid	$C_{23}H_{32}O_4$ 372.23004			
10223	Trace Natural	CBNDVA CBNDA-C3	cannabinodivarin cannabindiol-C3 homologue	$C_{20}H_{22}O_4$ 326.15179			
10224	Trace Natural	CBDOA CBDA-C1	cannabidiorcolic acid cannabidiol-C1 homologue acid	$C_{18}H_{22}O_4$ 302.15179			
10225	Trace Natural	CBDBA CBDA-C4	cannabidibutolic acid cannabidiol-C4 homologue acid	$C_{21}H_{28}O_4$ 344.19874			

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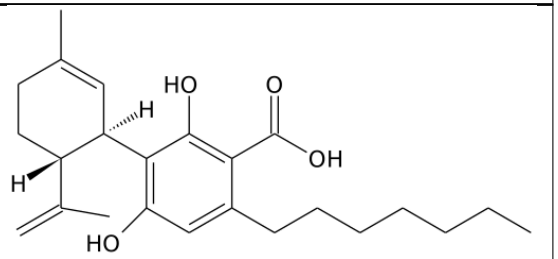
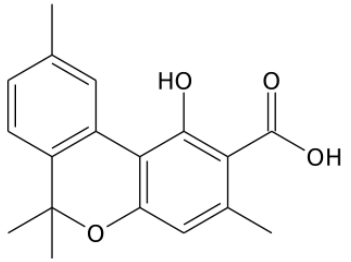
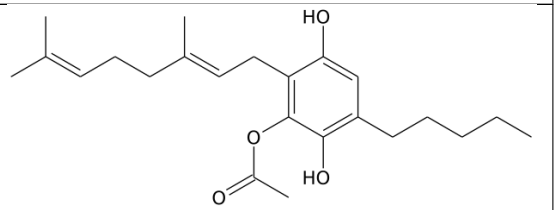
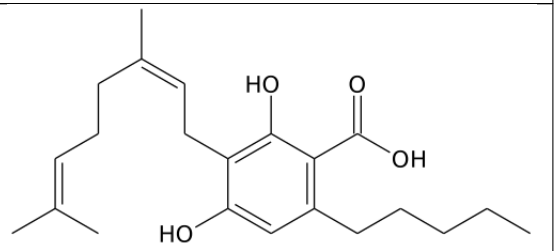
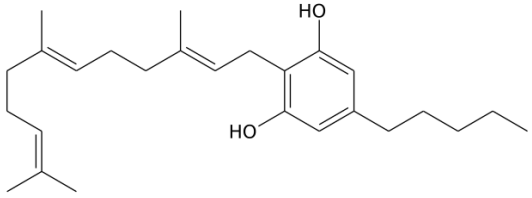
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10226	Trace Natural	CBDPA CBDA-C7	cannabidiphorolic acid cannabidiol-C7 homologue acid	$C_{23}H_{34}O_4$ 374.24569			
10227	Trace Natural	CBOA CBNA-C1	cannabiorcolic acid cannabinol-C1 homologue acid	$C_{18}H_{18}O_4$ 298.15179			
10030	Trace Natural	5-acetyl-4-OH-CBG	5-acetyl-4-hydroxycannabigerol	$C_{23}H_{34}O_4$ 374.517			
10050	Trace Natural		cannabinerolic acid	$C_{22}H_{32}O_4$ 360.949			
10064	Trace Natural		sesquicannabigerol	$C_{26}H_{40}O_2$ 384.302 1334308-58-5			

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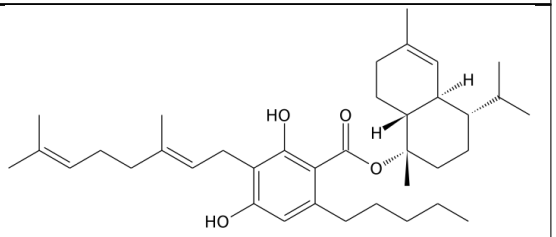
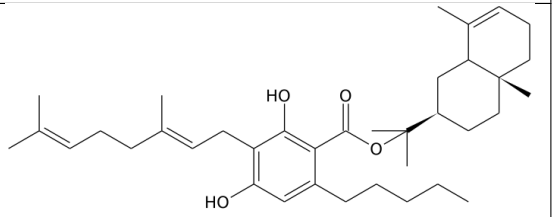
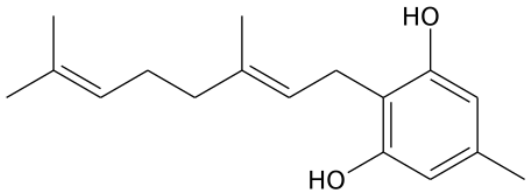
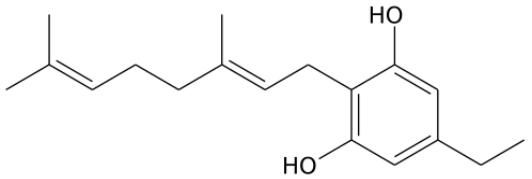
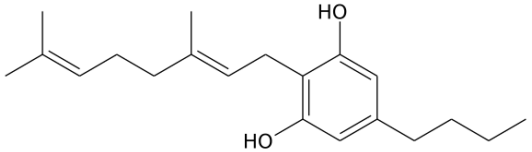
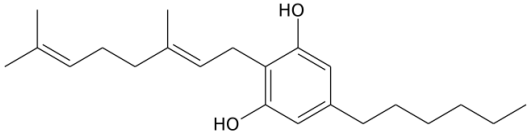
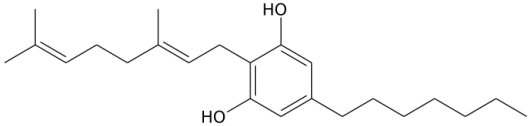
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10072	Trace Natural	a-cadinyl-CBGA	α-cadinyl-cannabigerolate	$C_{37}H_{56}O_4$ 564.418			
10077	Trace Natural	g-eudesmyl-CBGA	γ-eudesmyl-cannabigerolate	$C_{37}H_{56}O_4$ 564.844			
10178	Trace Natural	CBGO CBG-C1	Cannabigerorcol cannabigerol-C1 homologue	$C_{17}H_{24}O_2$ 260.17762			
10179	Trace Natural	CBGE CBG-C2	Cannabigerethol cannabigerol-C2 homologue	$C_{18}H_{26}O_2$ 274.19327			
10180	Trace Natural	CBGB CBG-C4	Cannabigerbutol cannabigerol-C4 homologue	$C_{20}H_{30}O_2$ 302.22457			
10181	Trace Natural	CBGH CBG-C6	Cannabigerhexol cannabigerol-C6 homologue	$C_{22}H_{34}O_2$ 330.25587			
10182	Trace Natural	CBGP CBG-C7	Cannabigerphorol cannabigerol-C7 homologue	$C_{23}H_{36}O_2$ 344.27152			

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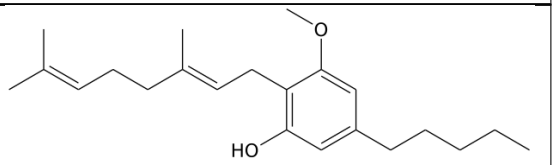
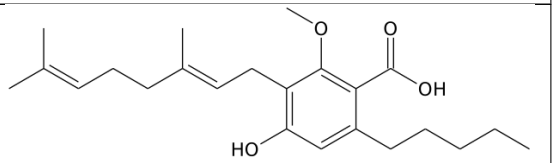
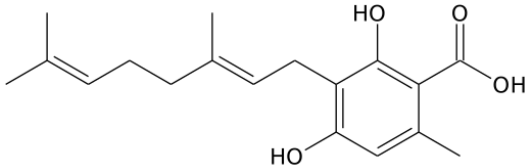
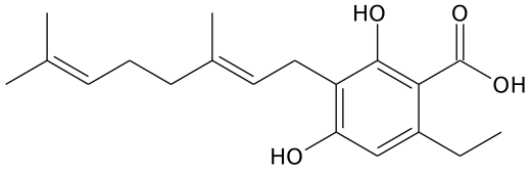
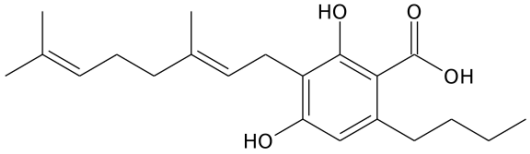
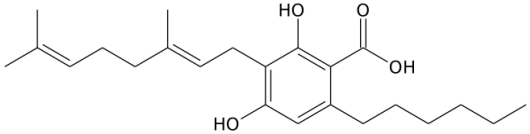
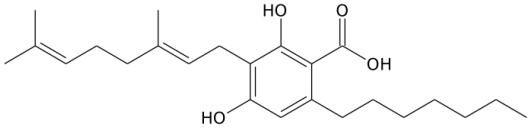
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10187	Trace Natural	CBGM	cannabigerol methyl ether	$C_{22}H_{34}O_2$ 330.25587			
10188	Trace Natural	CBGMA	cannabigerol methyl ether acid	$C_{23}H_{34}O_4$ 374.24569			
10218	Trace Natural	CBGOA CBGA-C1	Cannabigerorcolic acid cannabigerol-C1 homologue acid	$C_{18}H_{24}O_4$ 304.16744			
10219	Trace Natural	CBGEA CBGA-C2	Cannabigeretholic acid cannabigerol-C2 homologue acid	$C_{19}H_{26}O_4$ 318.18309			
10220	Trace Natural	CBGBA CBGA-C4	Cannabigerbutolic acid cannabigerol-C4 homologue acid	$C_{21}H_{30}O_4$ 346.21439			
10221	Trace Natural	CBGHA CBGA-C6	Cannabigerhexolic acid cannabigerol-C6 homologue acid	$C_{23}H_{34}O_4$ 374.24569			
10222	Trace Natural	CBGPA CBGA-C7	Cannabigerphorolic acid cannabigerol-C7 homologue acid	$C_{24}H_{36}O_4$ 388.26134			

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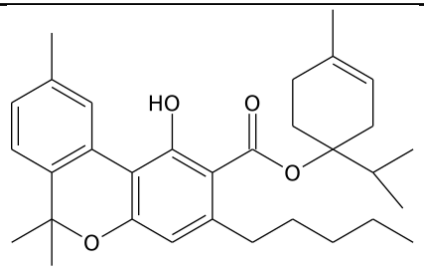
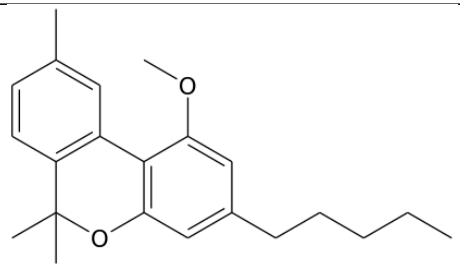
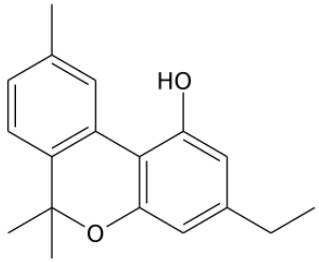
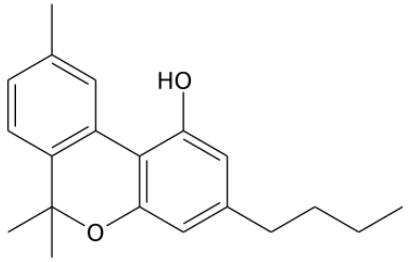
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10027	Trace Natural	4-terpenyl-CBNA	4-terpenyl-cannabinolate	$C_{32}H_{42}O_4$ 490.308			
10051	Trace Natural	CBNM	cannabinol methyl ether	$C_{22}H_{28}O_2$ 324.209 41935-92-6			
10052	Trace Natural	CBN-C2	cannabinol-C2 homologue	$C_{18}H_{20}O_2$ 268.146 99623-70-8			
10053	Trace Natural	CBN-C4 CBNB	cannabinol-C4 homologue Cannabutol	$C_{20}H_{24}O_2$ 296.178			

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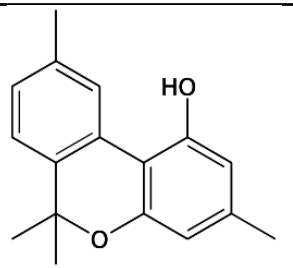
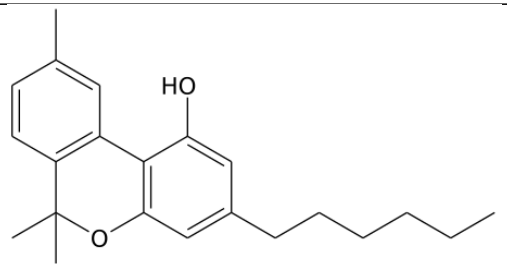
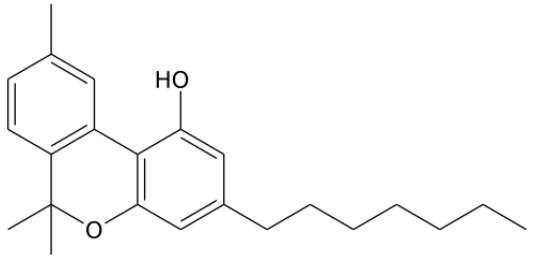
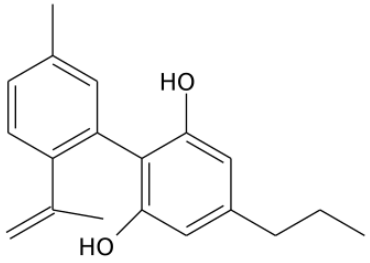
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10055	Trace Natural	CBN-C1 CBO	cannabiorcol Cannabinol-C1 homologue	$C_{17}H_{18}O_2$ 254.131 19825-73-1			
10171	Trace Natural	CBNH CBN-C6	Cannabihexol cannabinol-C6 homologue	$C_{22}H_{28}O_2$ 324.20892			
10172	Trace Natural	CBNP CBN-C7	Cannabiphorol cannabinol-C7 homologue	$C_{23}H_{30}O_2$ 338.22457			
10183	Trace Natural	CBNDV CBND-C3	cannabinodivarin cannabindiol-C3 homologue	$C_{19}H_{22}O_2$ 282.16197			

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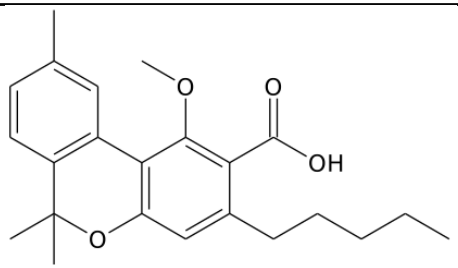
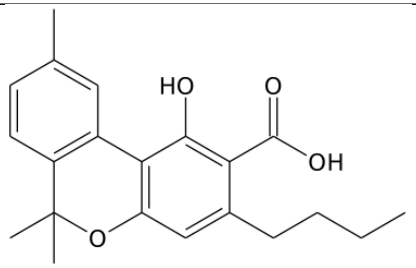
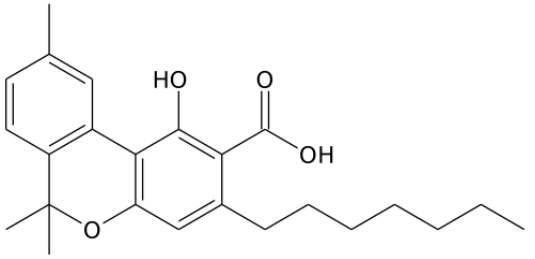
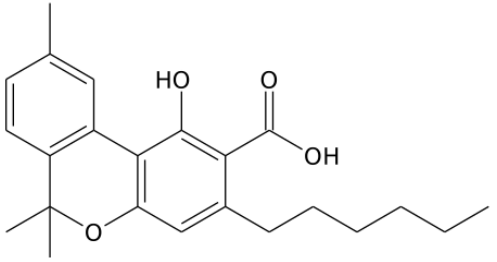
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10186	Trace Natural	CBNMA	cannabinol methyl ether acid	$C_{23}H_{28}O_4$ 368.19874			
10210	Trace Natural	CBNBA CBNA-C4	Cannabutolic acid cannabinol-C4 homologue acid	$C_{21}H_{24}O_4$ 340.16744			
10211	Trace Natural	CBNPA CBNA-C7	Cannabiphorolic acid cannabinol-C7 homologue acid	$C_{24}H_{30}O_4$ 382.21439			
10212	Trace Natural	CBNHA CBNA-C6	Cannabihexolic acid cannabinol-C6 homologue acid	$C_{23}H_{28}O_4$ 368.19874			

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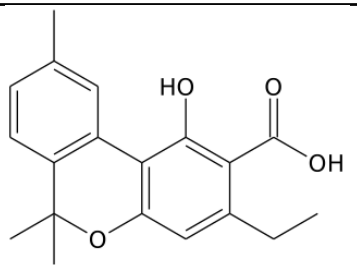
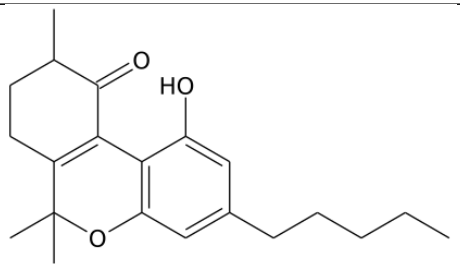
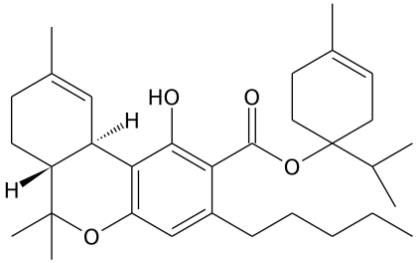
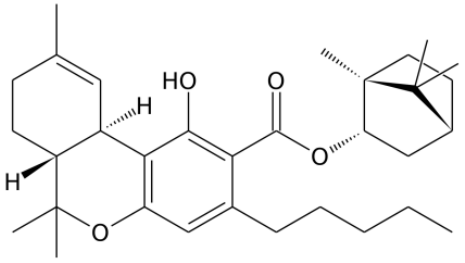
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10230	Trace Natural	CBNEA CBNA-C2	cannabinetholic acid cannabinol-C2 homologue acid	$C_{19}H_{20}O_4$ 312.146			
10022	Trace Natural	OTHC 10-O-d6a-THC	10-Oxo-Δ6a(10a)-Tetrahydrocannabinol	$C_{21}H_{28}O_3$ 328.449			
10028	Trace Natural	4-terpenyl-d9-THCA	4-terpenyl-Δ9-tetrahydrocannabinolate	$C_{32}H_{46}O_4$ 494.71			
10032	Trace Natural	bornyl-d9-THCA	bornyl-Δ9-tetrahydrocannabinolate	$C_{32}H_{46}O_4$ 494.71			

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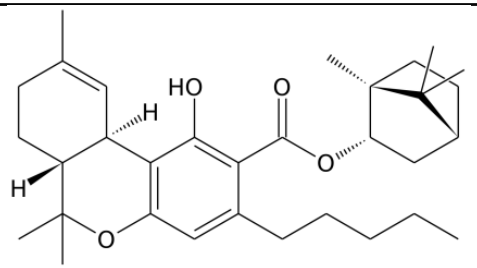
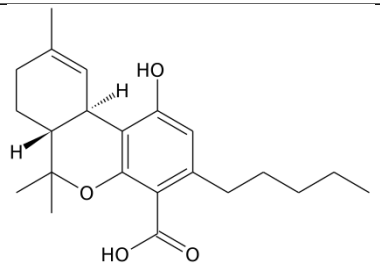
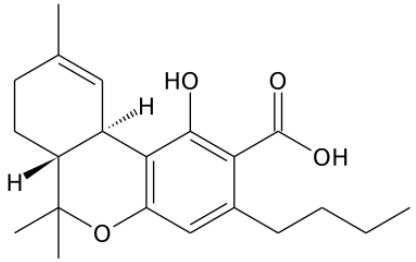
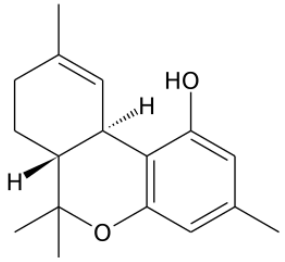
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10060	Trace Natural	epi-bornyl- d9-THCA	epi-bornyl-Δ9- tetrahydrocannabinolate	$C_{32}H_{46}O_4$ 494.71			
10065	Trace Natural	THCA-B d9-THCA-B	tetrahydrocannabinolic acid-B	$C_{22}H_{30}O_4$ 358.478			
10066	Trace Natural	THCBA d9-THCBA THCA-C4	tetrahydrocannabinolic acid-C4 homologue Tetrahydrocannabutolic acid	$C_{21}H_{28}O_4$ 344.2			
10067	Trace Natural	THCO d9-THCO THC-C1	tetrahydrocannabiorcol Tetrahydrocannabinol-C1 homologue	$C_{17}H_{22}O_2$ 258.361 22972-65-2			

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Table 1 – continued from previous page

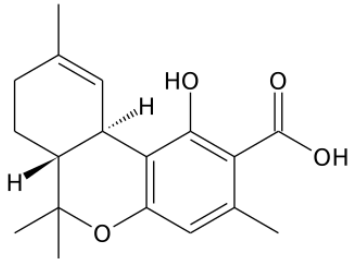
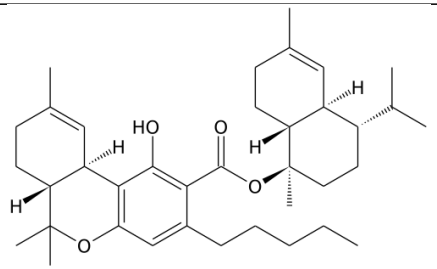
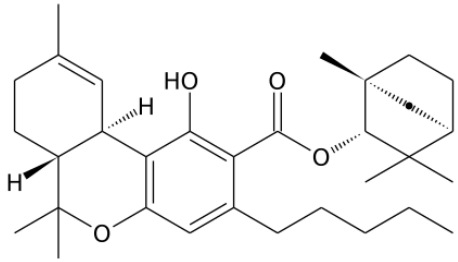
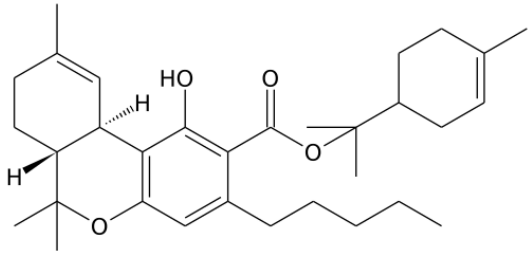
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10068	Trace Natural	THCOA d9-THCOA THCA-C1	tetrahydrocannabiorcolic acid Tetrahydrocannabinolic acid-C1 homologue	$C_{18}H_{22}O_4$ 302.152			
10073	Trace Natural	a-cadinyl- d9-THCA	α-cadinyl-Δ9- tetrahydrocannabinolate	$C_{37}H_{54}O_4$ 562.828			
10074	Trace Natural	a-fenchyl- d9-THCA	α-fenchyl-Δ9- tetrahydrocannabinolate	$C_{32}H_{46}O_4$ 494.71			
10075	Trace Natural	a-terpenyl- d9-THCA	α-terpenyl-Δ9- tetrahydrocannabinolate	$C_{32}H_{46}O_4$ 494.71			

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Table 1 – continued from previous page

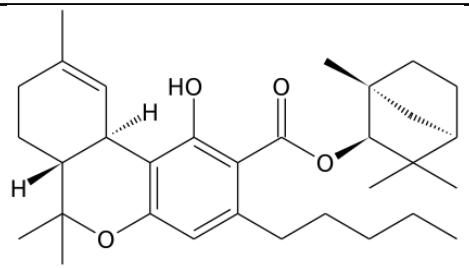
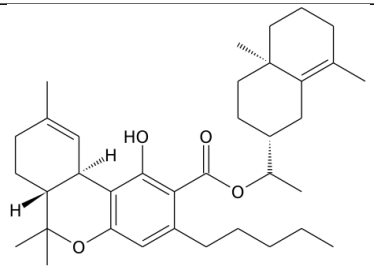
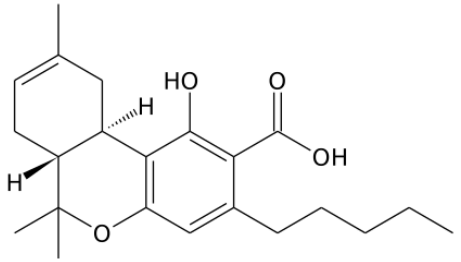
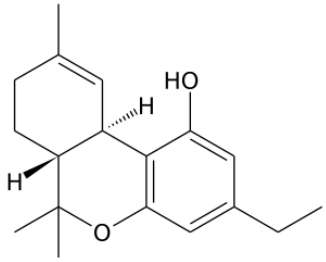
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10076	Trace Natural	b-fenchyl- d9-THCA	β-fenchyl-Δ9- tetrahydrocannabinolate	$C_{32}H_{46}O_4$ 494.71			
10078	Trace Natural	g-eudesmyl- d9-THCA	γ-eudesmyl-Δ9- tetrahydrocannobinolate	$C_{36}H_{52}O_4$ 548.801			
10080	Trace Natural	d8-THCA-A	Δ8- tetrahydrocannabinolic acid-A	$C_{22}H_{30}O_4$ 358.478 23978-89-4			
10168	Trace Natural	THCE d9-THCE d9-THC-C2	Δ9- tetrahydrocannabiethol Δ9-tetrahydrocannabinol- C2 homologue	$C_{18}H_{24}O_2$ 272.4			

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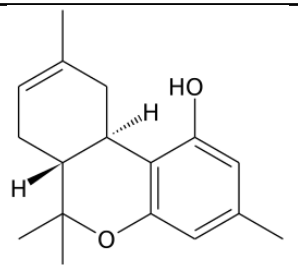
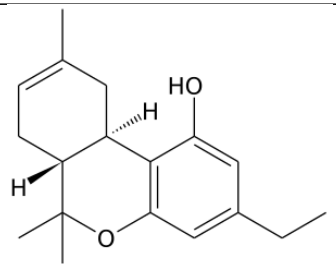
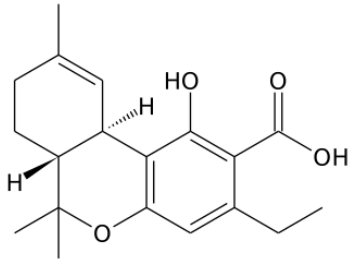
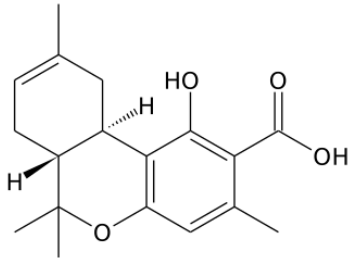
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10173	Trace Natural	d8-THCO d8-THC-C1	Δ8-tetrahydrocannabiorcol Δ8-tetrahydrocannabinol-C1 homologue	$C_{17}H_{22}O_2$ 258.16197			
10174	Trace Natural	d8-THCE d8-THC-C2	Δ8-tetrahydrocannabiethol Δ8-tetrahydrocannabinol-C2 homologue	$C_{18}H_{24}O_2$ 272.17762			
10207	Trace Natural	THCEA d9-THCEA d9-THCA-C2	tetrahydrocannabietholic acid Δ9-tetrahydrocannabietholic acid Δ9-tetrahydrocannabinol-C2 homolgue acid,	$C_{19}H_{24}O_4$ 316.16744			
10213	Trace Natural	d8-THCOA d8-THCA-C1	Δ8-tetrahydrocannabiorcolic acid Δ8-tetrahydrocannabinol-C1 homologue acid	$C_{18}H_{22}O_4$ 302.15179			

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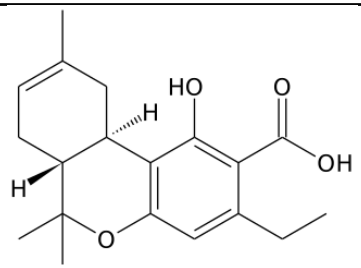
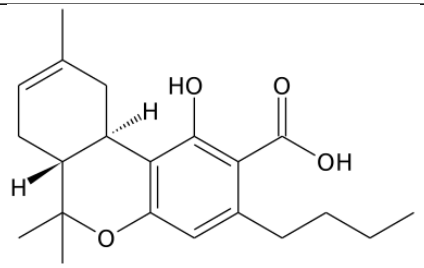
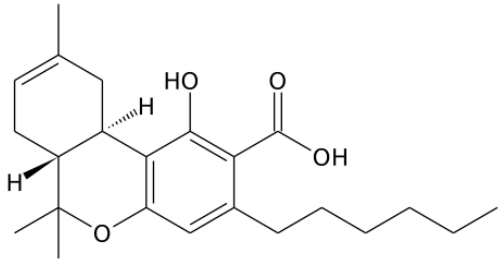
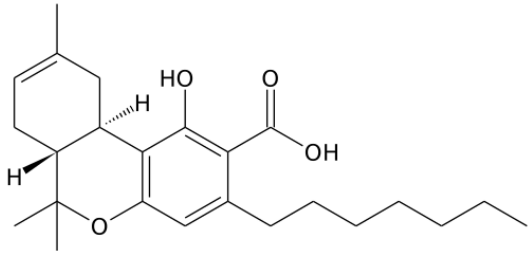
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10214	Trace Natural	d8-THCEA d8-THCA-C2	Δ8-tetrahydrocannabietholic acid Δ8-tetrahydrocannabinol-C2 homologue acid	$C_{19}H_{24}O_4$ 316.16744			
10215	Trace Natural	d8-THCBA d8-THCA-C4	Δ8-tetrahydrocannabutolic acid Δ8-tetrahydrocannabinol-C4 homologue acid	$C_{21}H_{28}O_4$ 344.19874			
10216	Trace Natural	d8-THCHA d8-THCA-C6	Δ8-tetrahydrocannabihexolic acid Δ8-tetrahydrocannabinol-C6 homologue acid	$C_{23}H_{32}O_4$ 372.23004			
10217	Trace Natural	d8-THCPA d8-THCA-C7	Δ8-tetrahydrocannabiphorolic acid Δ8-tetrahydrocannabinol-C7 homologue acid	$C_{24}H_{34}O_4$ 386.24569			

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Table 1 – continued from previous page

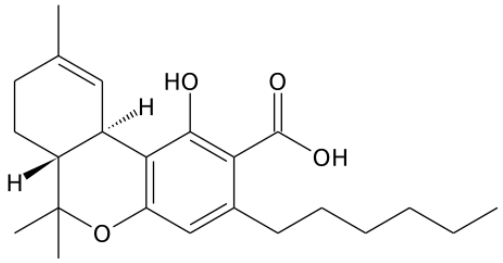
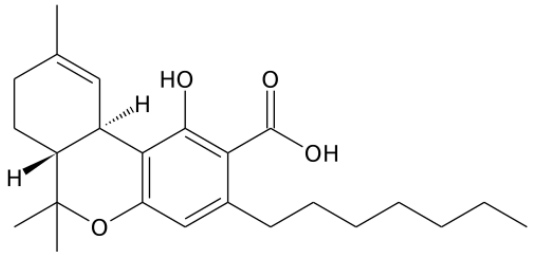
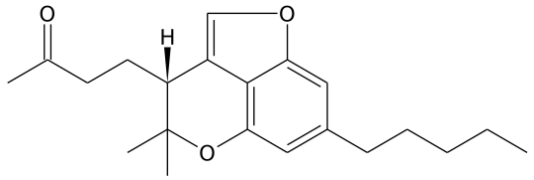
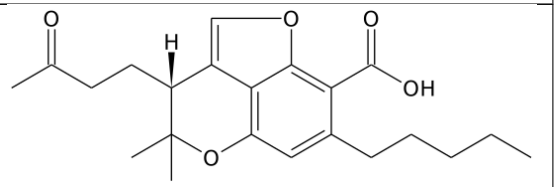
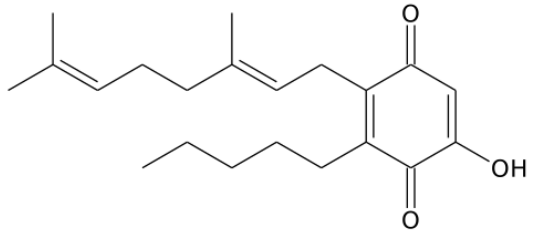
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10228	Trace Natural	THCHA THCA-C6 d9-THCHA d9-THCA-C6	tetrahydrocannabihexolic acid tetrahydrocannabinol-C6 homologue acid Δ9-tetrahydrocannabihexolic acid Δ9-tetrahydrocannabinol-C6 homologue acid	$C_{23}H_{32}O_4$ 372.23004			
10229	Trace Natural	THCPA THCA-C7 d9-THCPA d9-THCA-C7	tetrahydrocannabiphorolic acid tetrahydrocannabinol-C7 homologue acid Δ9-tetrahydrocannabiphorolic acid Δ9-tetrahydrocannabinol-C7 homologue acid	$C_{24}H_{34}O_4$ 396.24569			
10020	Trace Natural		(-)-cannabicourmarone	$C_{21}H_{28}O_3$ 328.449 70474-97-4			
10021	Trace Natural		(-)-cannabicourmaronic acid	$C_{22}H_{28}O_5$ 372.459 20408-52-0			
10023	Trace Natural		2-geranyl-5-hydroxy-3-n-pentyl-1,4-benzoquinone	$C_{21}H_{30}O_3$ 330.219			

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Table 1 – continued from previous page

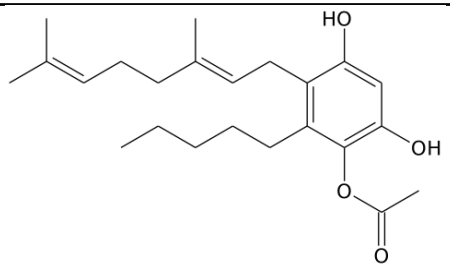
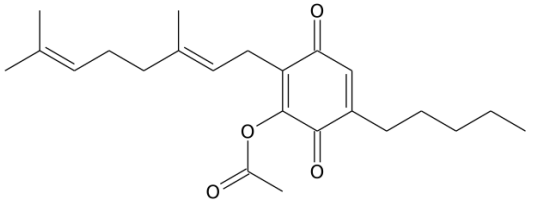
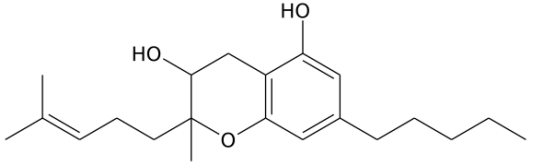
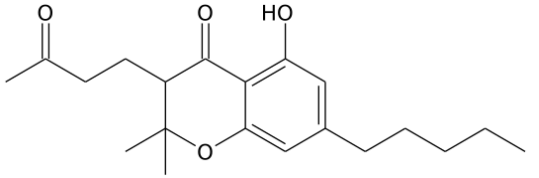
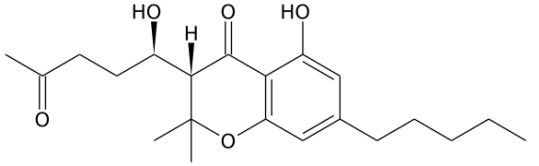
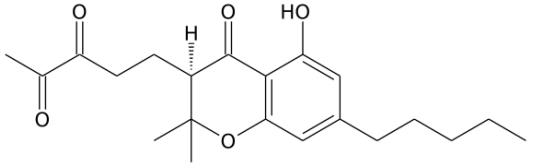
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10025	Trace Natural		4-acetoxy-2-geranyl-5-hydroxy-3-n-pentylphenol	$C_{23}H_{34}O_4$ 374.246			
10029	Trace Natural		5-acetoxy-6-geranyl-3-n-pentyl-1,4-benzoquinone	$C_{23}H_{32}O_4$ 372.23			
10031	Trace Natural	7-OH-cannabichromene	7-hydroxycannabichromane	$C_{21}H_{32}O_3$ 332.48 1134497-17-8			
10033	Trace Natural	CBCN	cannabichromanone	$C_{20}H_{28}O_4$ 332.199 56154-57-5			
10034	Trace Natural	CBCN-B	cannabichromanone-B	$C_{21}H_{30}O_5$ 362.463			
10035	Trace Natural	CBCN-C	cannabichromanone-C	$C_{21}H_{28}O_5$ 360.448			

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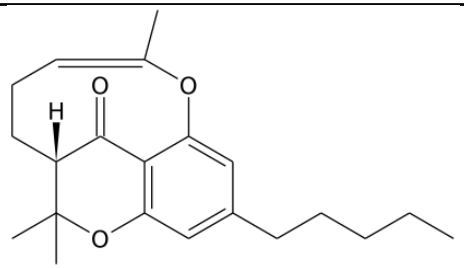
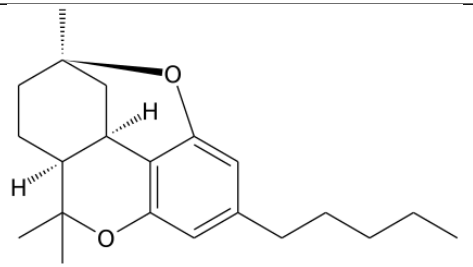
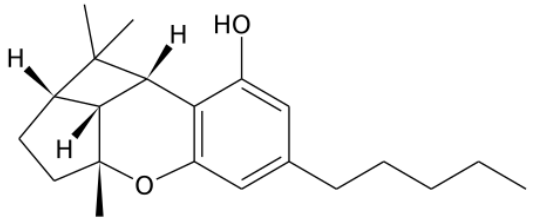
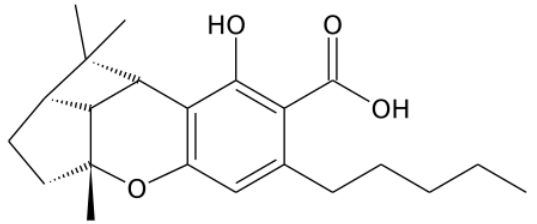
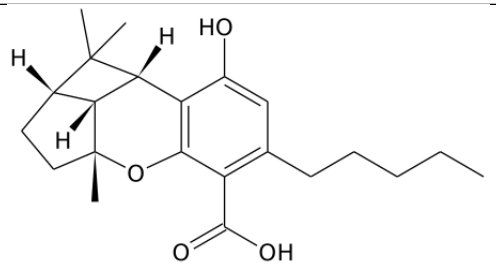
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10036	Trace Natural	CBCN-D	cannabichromanone-D	$C_{21}H_{28}O_3$ 328.449			
10037	Trace Natural	CBR CBTC	cannabicitran	$C_{21}H_{30}O_2$ 314.465 19352-64-8			
10039	Trace Natural	CBL	cannabicyclol	$C_{21}H_{30}O_2$ 314.469 21366-63-2			
10040	Trace Natural	CBLA-A	cannabicyclolic acid A	$C_{22}H_{30}O_4$ 358.214			
10041	Trace Natural	CBLA-B	cannabicyclolic acid B	$C_{22}H_{30}O_4$ 358.214			

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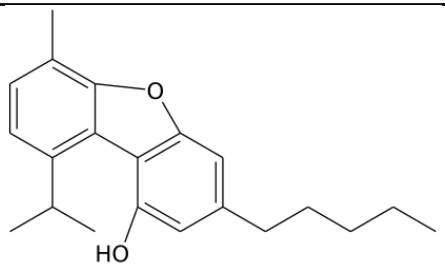
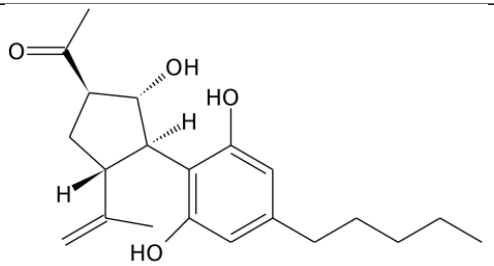
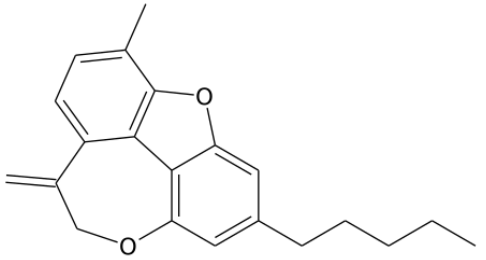
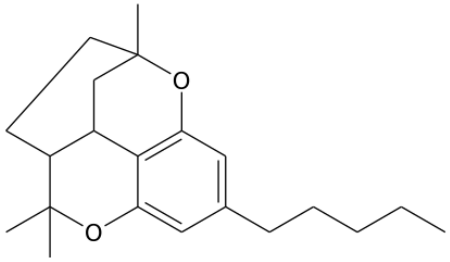
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10048	Trace Natural	CBF	cannabifuran	$C_{21}H_{30}O_2$ 314.224 56154-58-6			
10049	Trace Natural	CBM	cannabimovone	$C_{21}H_{30}O_4$ 346.467			
10054	Trace Natural	CBX	cannabioxepane	$C_{21}H_{30}O_5$ 362.463			
10056	Trace Natural	CBR	cannabiripsol	$C_{21}H_{32}O_4$ 348.483 72236-32-9			

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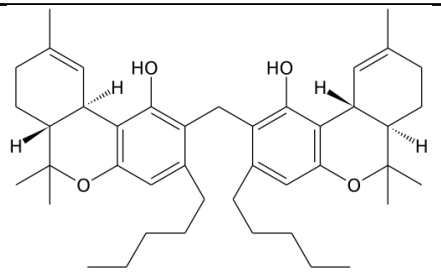
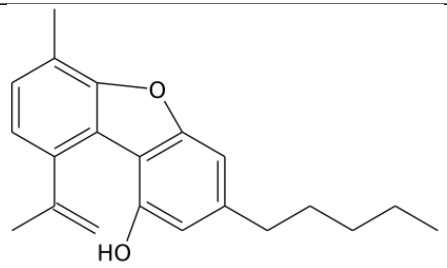
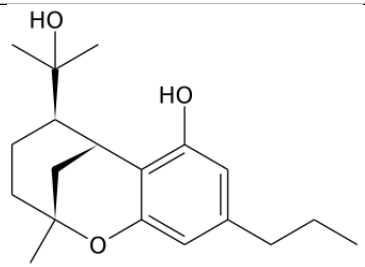
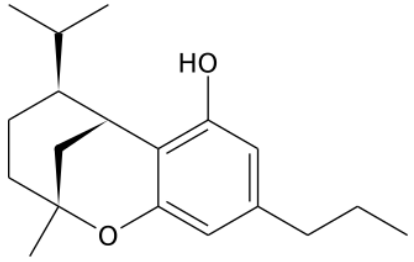
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10057	Trace Natural		cannabisol	$C_{43}H_{60}O_4$ 640.941 1384106-31-3			
10059	Trace Natural	DCBF	dehdyrocannabifuran	$C_{21}H_{24}O_2$ 308.178			
10061	Trace Natural	OH-iso-HHCV	Cannabiglendovarin Hydroxy-iso-hexahydrocannabivarin	$C_{19}H_{28}O_3$ 298.38			
10062	Trace Natural	iso-HHCV	iso-hexahydrocannabivarin	$C_{19}H_{28}O_2$ 288.4			

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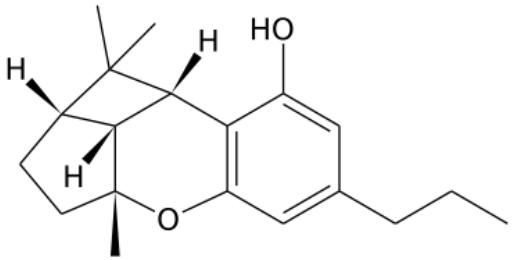
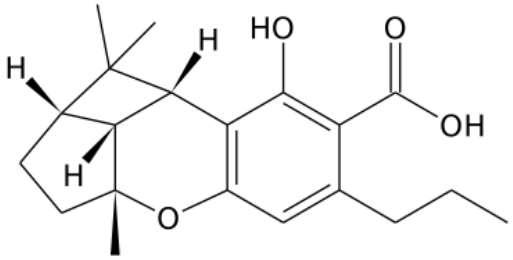
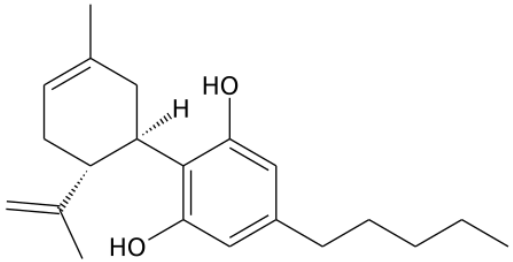
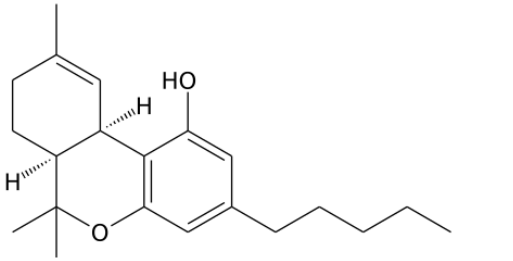
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10198	Trace Natural	CBLV CBL-C3	cannabicyclovarin cannabicyclol-C3 homologue	$C_{19}H_{26}O_2$ 286.193			
10199	Trace Natural	CBLVA CBLA-C3	cannabicyclovarinic acid cannabicylolic acid-C3 homologue	$C_{20}H_{26}O_4$ 330.183			
10106	Semi-Synthetic + Trace Natural	d6-CBD	Δ6-cannabidiol	$C_{21}H_{30}O_2$ 314.469 95588-88-8			
10058	Semi-Synthetic + Trace Natural	cis-d9-THC	cis-Δ9-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 6087-73-6			

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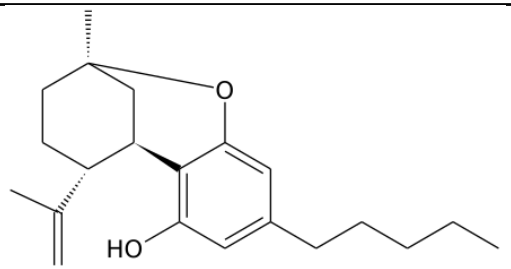
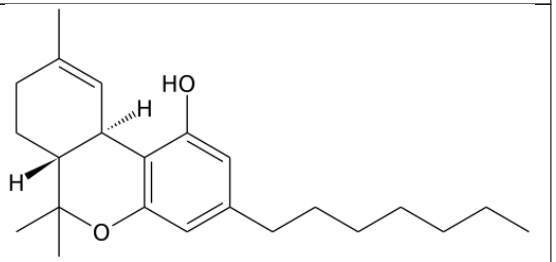
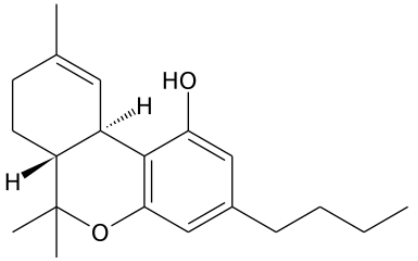
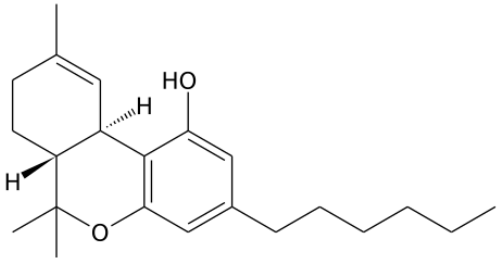
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10063	Semi-Synthetic + Trace Natural	iso-THC	isotetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469			
10069	Semi-Synthetic + Trace Natural	THCP d9-THCP THC-C7	Δ9- tetrahydrocannabiphorol	$C_{23}H_{34}O_2$ 342.523 54763-99-4			
10070	Semi-Synthetic + Trace Natural	THCB d9-THCB THC-C4	Δ9-tetrahydrocannabutol	$C_{20}H_{28}O_2$ 300.442 60008-00-6			
10071	Semi-Synthetic + Trace Natural	THCH d9-THCH THC-C6	Δ9-tetrahydrocannahexol	$C_{22}H_{32}O_2$ 328.496 36482-24-3			

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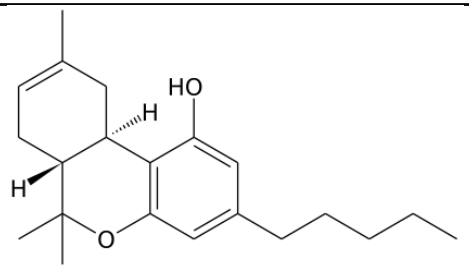
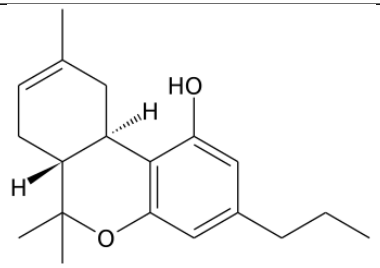
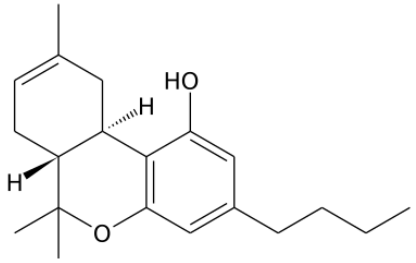
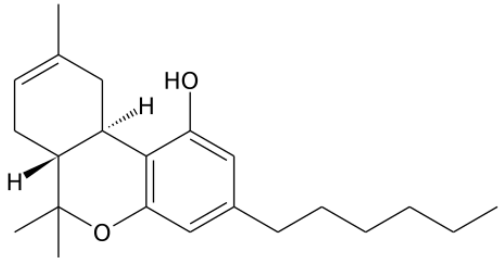
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10079	Semi-Synthetic + Trace Natural	d8-THC	Δ8-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 5957-75-5			
10165	Semi-Synthetic + Trace Natural	d8-THCV d8-THC-C3	Δ8-tetrahydrocannabivarin Δ8-tetrahydrocannabinol homologue	$C_{19}H_{26}O_2$ 286.415			
10175	Semi-Synthetic + Trace Natural	d8-THCB d8-THC-C4 JWH-130	Δ8-tetrahydrocannabutol,Δ8-tetrahydrocannabinol-C4 homologue	$C_{20}H_{28}O_2$ 300.20892			
10176	Semi-Synthetic + Trace Natural	d8-THCH d8-THC-C6 JWH-124	Δ8-tetrahydrocannabihexol Δ8-tetrahydrocannabinol-C6 homologue	$C_{22}H_{32}O_2$ 328.24022			

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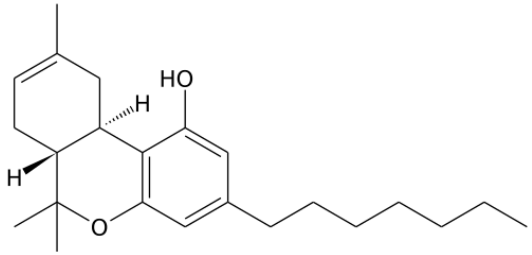
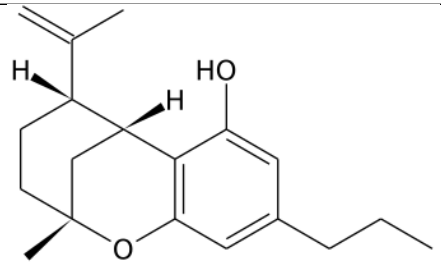
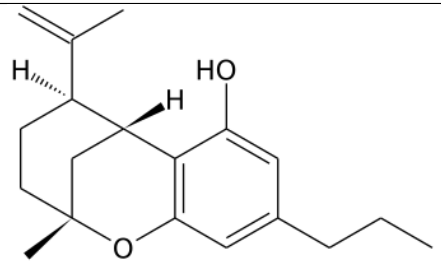
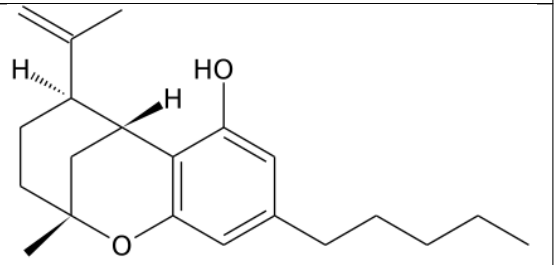
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10177	Semi-Synthetic + Trace Natural	d8-THCP d8-THC-C7 JWH-081	Δ8-tetrahydrocannabiphorol Δ8-tetrahydrocannabinol-C7 homologue	$C_{23}H_{34}O_2$ 342.25587			
10195	Semi-Synthetic + Trace Natural	d7-cis-iso-THCV	Δ7-cis-isotetrahydrocannabinovarin	$C_{19}H_{26}O_2$ 286.415			
10196	Semi-Synthetic + Trace Natural	d7-trans-iso-THCV	Δ7-trans-isotetrahydrocannabinovarin	$C_{19}H_{26}O_2$ 286.415			
10197	Semi-Synthetic + Trace Natural	d7-trans-iso-THC	Δ7—isotetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469			

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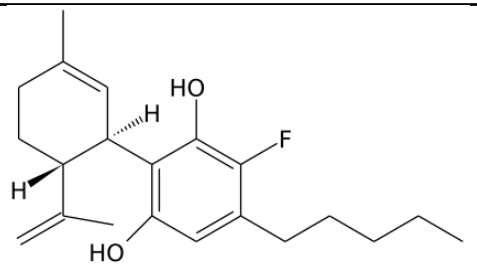
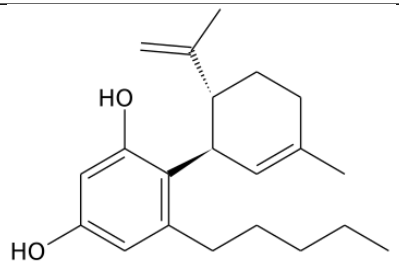
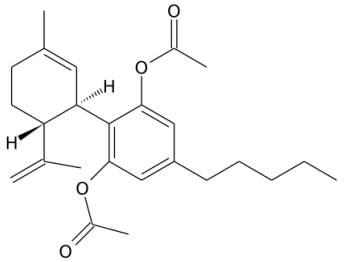
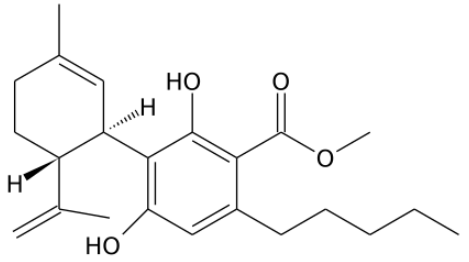
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10085	Semi-Synthetic	4'-F-CBD PECS-101 HUF-101 HU-474	4'-Fluorocannabidiol	$C_{21}H_{29}FO_2$ 332.459 1619228-89-5			
10088	Semi-Synthetic	Abn-CBD	abnormal cannabidiol	$C_{21}H_{30}O_2$ 314.469 22972-55-0			
10090	Semi-Synthetic	CBD-di-O-Ac CBD-DO	Cannabidiol diacetate	$C_{25}H_{34}O_4$ 398.543			
10092	Semi-Synthetic	CBDA methyl ester	cannabidiolic acid methyl ester	$C_{23}H_{32}O_4$ 372.5 55658-71-4			

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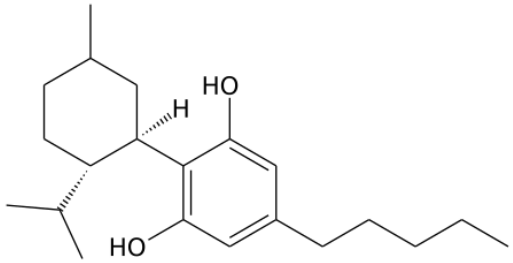
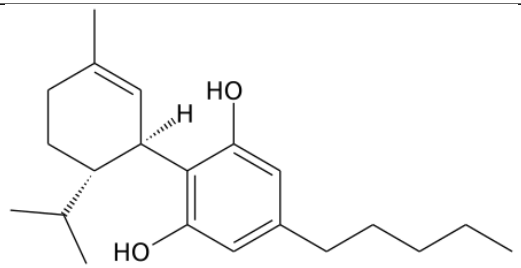
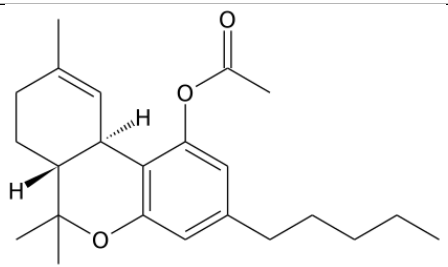
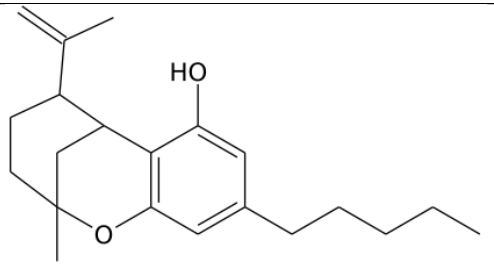
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10098	Semi-Synthetic	H4-CBD THCBD	tetrahydrocannabidiol	$C_{21}H_{34}O_2$ 318.501 4460-20-2			
10166	Semi-Synthetic	H2-CBD	8,9-dihydrocannabidiol	$C_{21}H_{30}O_2$ 314.469			
10099	Semi-Synthetic	THC-O-Ac d9-THC-O-acetate	Tetrahydrocannabinol-O-acetate Δ9-tetrahydrocannabinol-O-acetate	$C_{23}H_{32}O_3$ 356.506 23132-17-4			
10100	Semi-Synthetic	trans-iso-d7-THC	trans-iso-d7-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.465			

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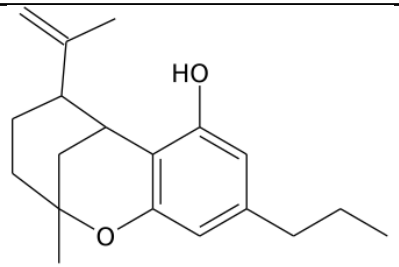
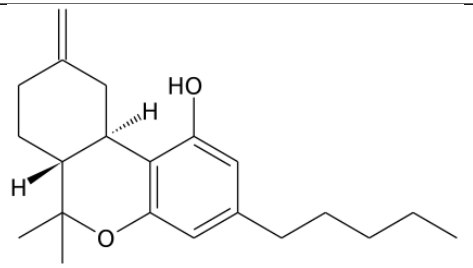
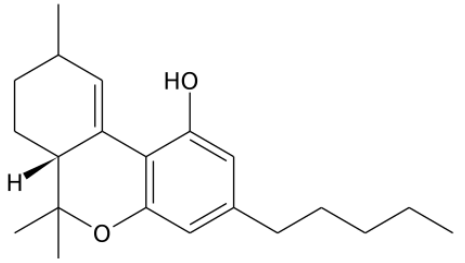
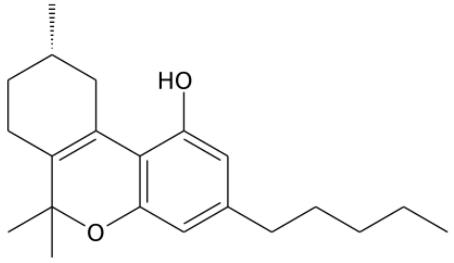
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10101	Semi-Synthetic	trans-iso-d7-THCV	trans-iso-d7-tetrahydrocannabivarin	$C_{19}H_{26}O_2$ 286.412			
10102	Semi-Synthetic	d11-THC exo-THC	Δ-11-Tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 16849-44-8			
10103	Semi-Synthetic	d10-THC	Δ10-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 95543-62-7			
10104	Semi-Synthetic	d3-THC	Δ3-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 10330559			

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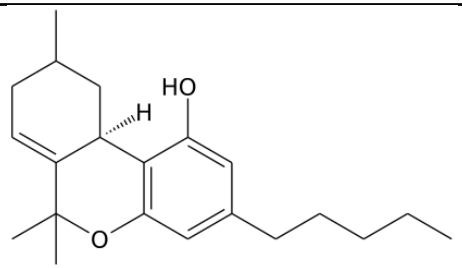
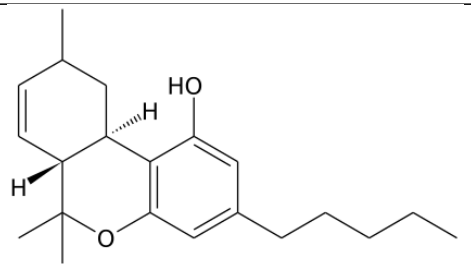
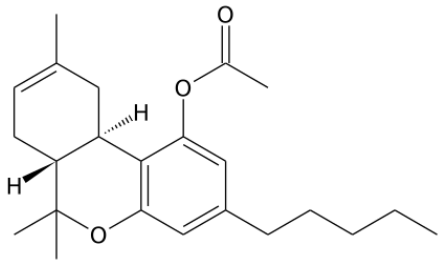
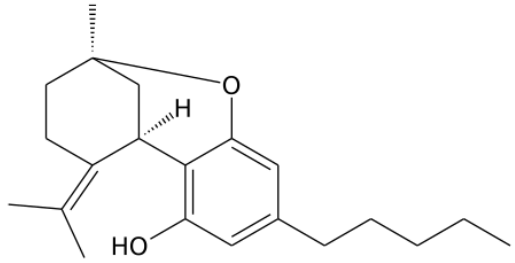
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10105	Semi-Synthetic	d4-THC	Δ4-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 59042-44-3			
10107	Semi-Synthetic	d7-THC	Δ7-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469 162678-94-6			
10108	Semi-Synthetic	d8-THC-O-Ac	Δ8-tetrahydrocannabinol-O-acetate	$C_{23}H_{32}O_3$ 356.506 23050-54-6			
10157	Semi-Synthetic	d4,8-iso-THC	Δ4,8-iso-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469			

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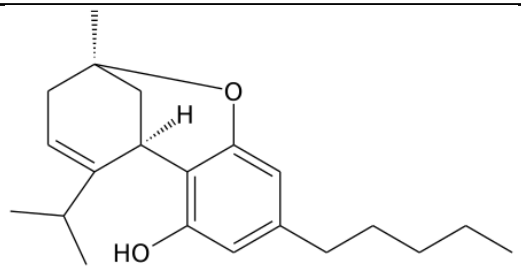
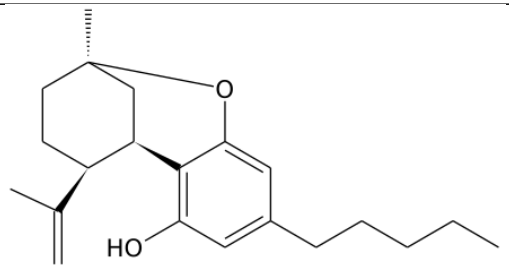
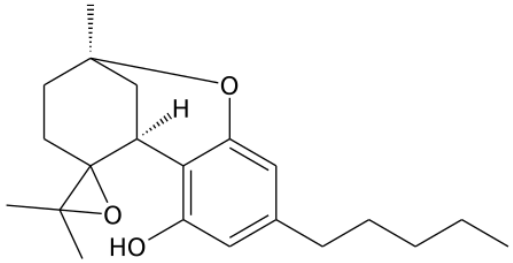
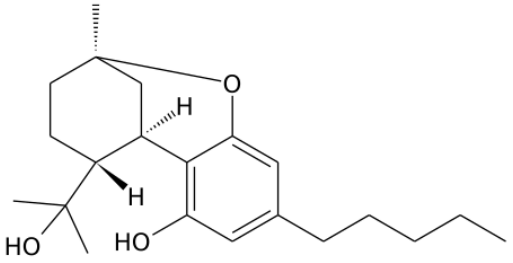
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10158	Semi-Synthetic	d4-iso-THC	Δ8-iso-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469			
10159	Semi-Synthetic	d8-cis-iso-THC	Δ8-cis-iso-tetrahydrocannabinol	$C_{21}H_{30}O_2$ 314.469			
10160	Semi-Synthetic	4,8-epoxy-iso-THC	4,8-epoxy-iso-tetrahydrocannabinol	$C_{21}H_{30}O_3$ 330.219			
10161	Semi-Synthetic	8-OH-iso-THC	8-hydroxy-iso-tetrahydrocannabinol	$C_{21}H_{32}O_3$ 332.235			

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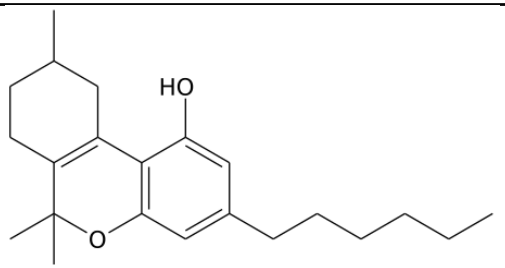
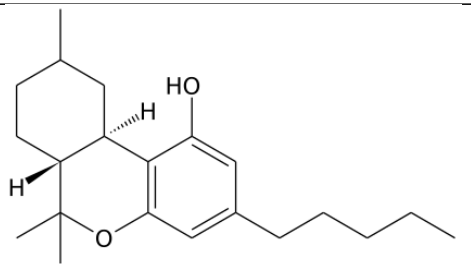
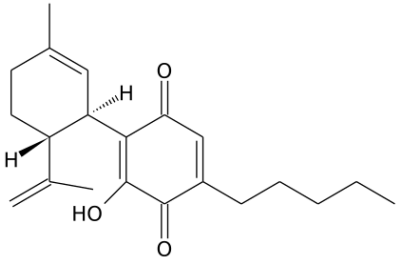
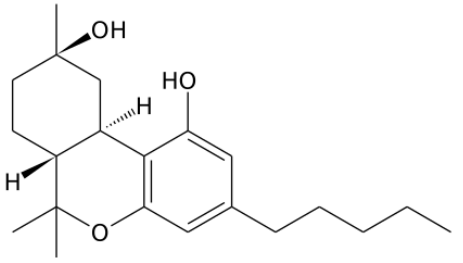
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10204	Semi-Synthetic	d6a,10a-THCH d6a,10a-THC-C6	Parahexyl synhexyl Δ6a,10a-tetrahydrocannabihexol Δ6a,10a-tetrahydrocannabinol-C6 homologue	$C_{22}H_{32}O_2$ 328.496 117-51-1			
10093	Semi-Synthetic	HHC	hexahydrocannabinol	$C_{21}H_{32}O_2$ 316.485 6692-85-9			
10112	Semi-Synthetic	HU-331		$C_{21}H_{28}O_3$ 328.445 137252-25-6			
10162	Semi-Synthetic	9-b-OH-HHC	9-β-hydroxy-hexahydrocannabinol	$C_{21}H_{32}O_3$ 332.235			

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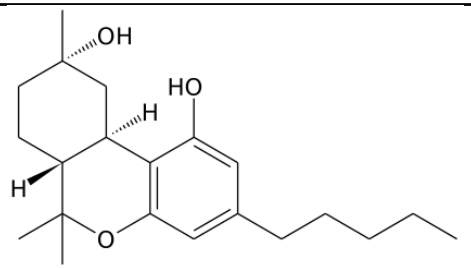
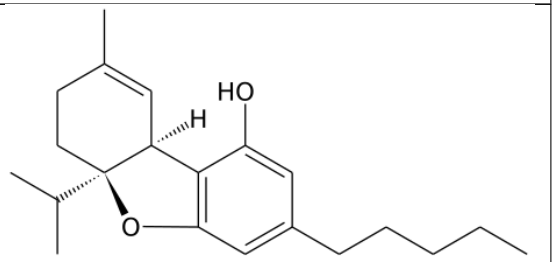
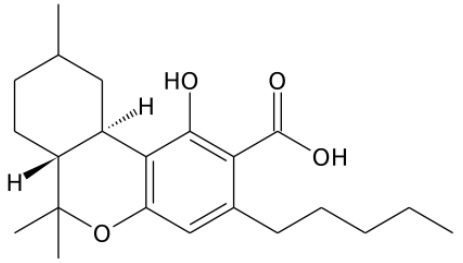
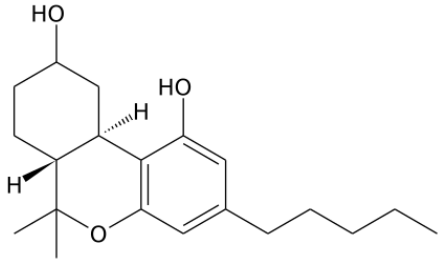
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10163	Semi-Synthetic	9-a-OH-HHC	9-α-hydroxy-hexahydrocannabinol	$C_{21}H_{32}O_3$ 332.235			
10164	Semi-Synthetic	iso-THCBF	iso-tetrahydrocannabifuran	$C_{21}H_{30}O_2$ 314.469			
10167	Semi-Synthetic	HHCA	hexahydrocannabinolic acid	$C_{22}H_{32}O_4$ 360.23			
10191	Semi-Synthetic	9-nor-9-OH-HHC	9-nor-9-hydroxyhexahydrocannabinol	$C_{20}H_{30}O_3$ 318.219			

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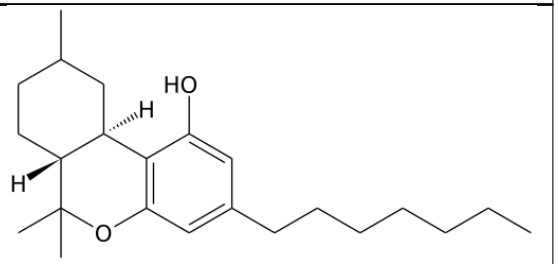
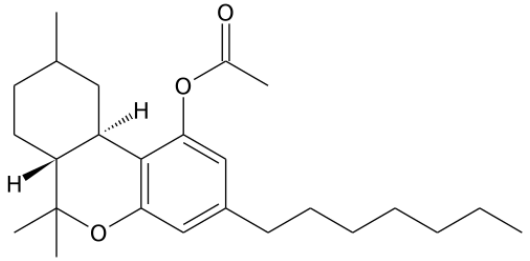
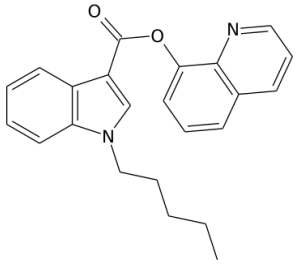
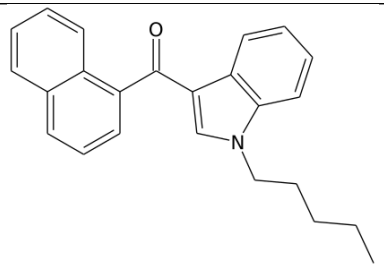
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10205	Semi-Synthetic	HHCP HHC-C7	hexahydrocannabiphorol hexahydrocannabinol-C7 homologue	$C_{23}H_{36}O_2$ 344.539			
10206	Semi-Synthetic	HHCP-O-Ac HHC-C7-O-Ac	hexahydrocannabiphorol-O-acetate hexahydrocannabinol-O-acetate-C7 homologue	$C_{25}H_{38}O_3$ 386.576			
10081	Fully Synthetic	PB-22 QUPIC SGT-21	1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester	$C_{23}H_{22}N_2O_2$ 358.441 1400742-17-7			
10082	Fully Synthetic	JWH-018 NA-PIMO AM-678	1-pentyl-3-(1-naphthoyl)indole	$C_{24}H_{23}NO$ 341.454 3983520			

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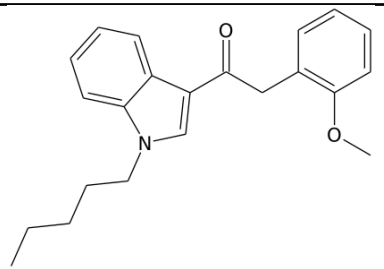
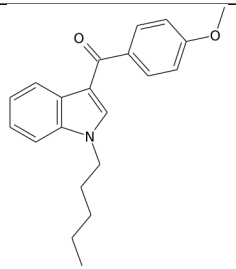
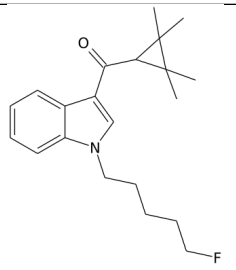
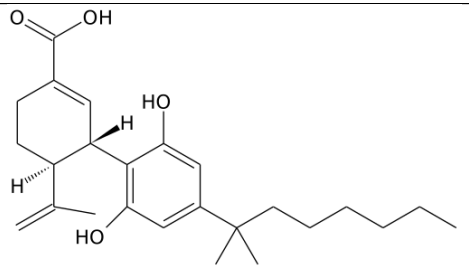
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10083	Fully Synthetic	JWH-250	1-pentyl-3-(2-methoxyphenylacetyl)indole	$C_{22}H_{25}NO_2$ 335.447 864445-43-2			
10084	Fully Synthetic	RCS-4	1-pentyl-3-(4-methoxybenzoyl)indole	$C_{21}H_{23}NO_2$ 321.42 1345966-78-0			
10086	Fully Synthetic	XLR-11	”5””-fluoro-UR-144 5F-UR-144”	$C_{21}H_{28}FNO$ 329.459 1364933-54-9			
10087	Fully Synthetic	HU-320	7-nor-7-carboxy-CBD-1,1-DMH	$C_{25}H_{36}O_4$ 400.559			

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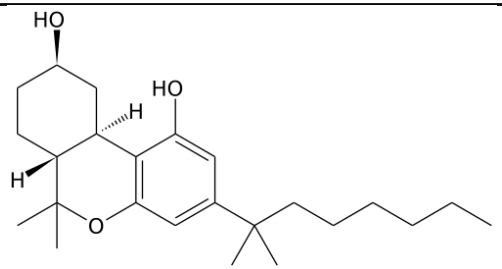
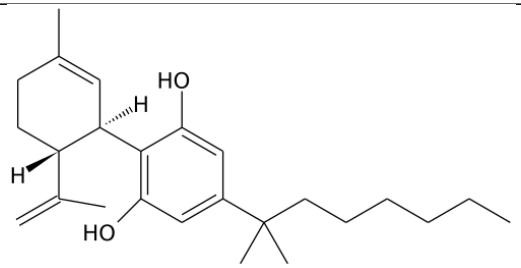
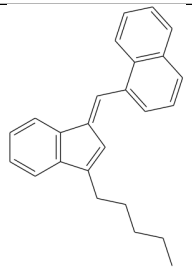
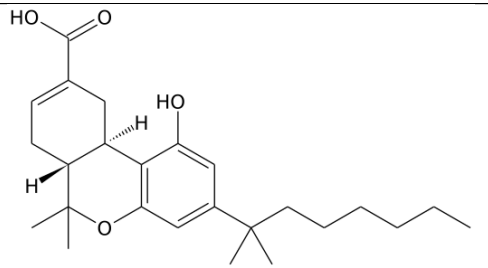
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10089	Fully Synthetic		canbisol Nabidrox	$C_{24}H_{38}O_3$ 374.565 56689-43-1			
10091	Fully Synthetic	CBD-DMH	Cannabidiol- dimethylheptyl	$C_{25}H_{38}O_2$ 370.577 97452-63-6			
10094	Fully Synthetic	JWH-176	JWH-176	$C_{25}H_{24}$ 324.467 619294-62-1			
10095	Fully Synthetic	HU-239 IP-751 CPL 7075 CT-3 JBT-101	Lenabasum ajulemic acid 1',1'-dimethylheptyl-delta- 8-tetrahydrocannabinol- 11-oic acid Anabasum Resunab	$C_{25}H_{36}O_4$ 400.559 137945-48-3			

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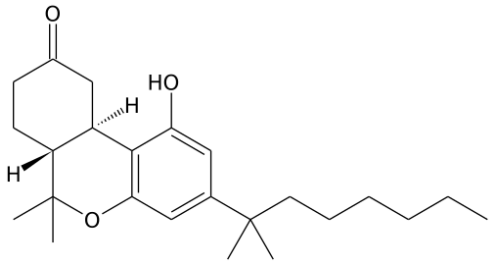
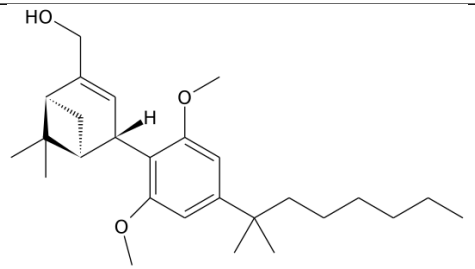
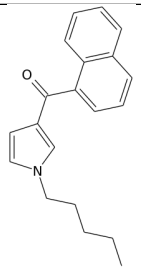
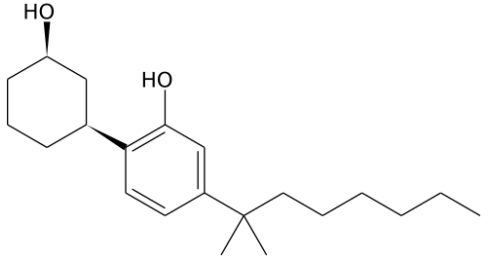
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10096	Fully Synthetic		Nabilone Cesamet	$C_{24}H_{36}O_3$ 372.549 51022-71-0			
10097	Fully Synthetic	HU-308 PPP-003	Onternabez	$C_{27}H_{42}O_3$ 414.63 256934-39-1			
10109	Fully Synthetic	JWH-030		$C_{20}H_{21}NO$ 291.394 162934-73-8			
10110	Fully Synthetic	CP 47,497		$C_{21}H_{34}O_2$ 318.501 70434-82-1			

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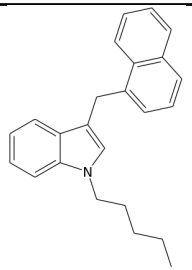
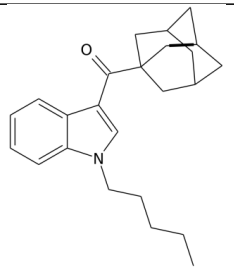
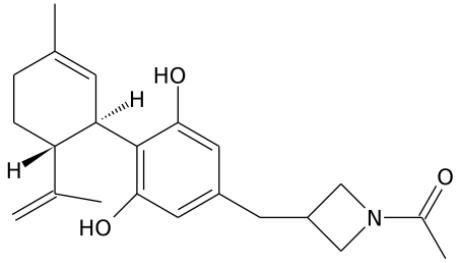
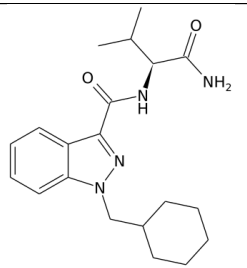
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10111	Fully Synthetic	JWH-175		$C_{24}H_{25}N$ 327.471 619294-35-8			
10113	Fully Synthetic	AB-001		$C_{24}H_{31}NO$ 349.518 1345973-49-0			
10114	Fully Synthetic	KLS-13019		$C_{22}H_{29}NO_3$ 355.478 1801243-39-9			
10115	Fully Synthetic	AB-CHMINACA		$C_{20}H_{28}N_4O_2$ 356.47 1185887-21-1			

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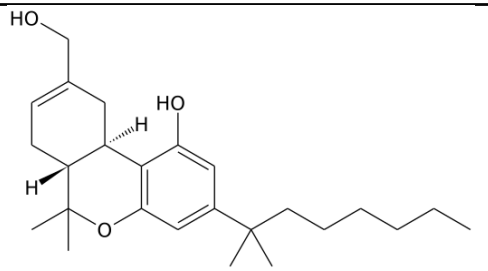
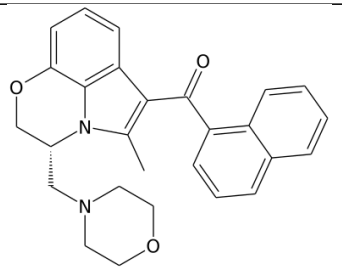
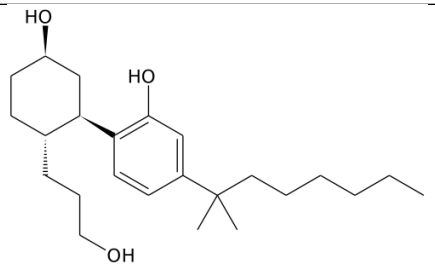
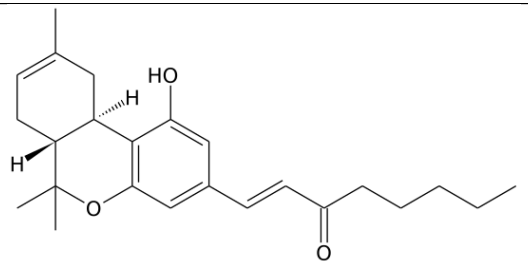
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10116	Fully Synthetic	HU-210		$C_{25}H_{38}O_3$ 386.576 112830-95-2			
10155	Fully Synthetic	WIN 55,212-2		$C_{27}H_{26}N_2O_3$ 426.516 131543-22-1			
10156	Fully Synthetic	CP 55,940		$C_{24}H_{40}O_3$ 376.581 5685460			
10200	Fully Synthetic	1,2-didehydro-3-oxo-THCO	1,2-didehydro-3-oxo-Δ8-tetrahydrocannabiocyl	$C_{24}H_{32}O_3$ 368.517			

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Table 1 – continued from previous page

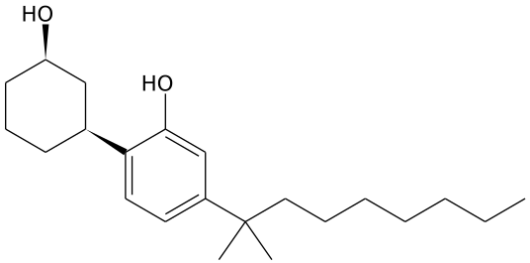
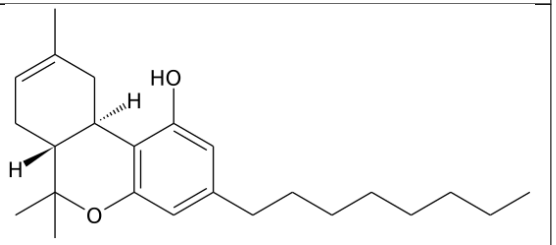
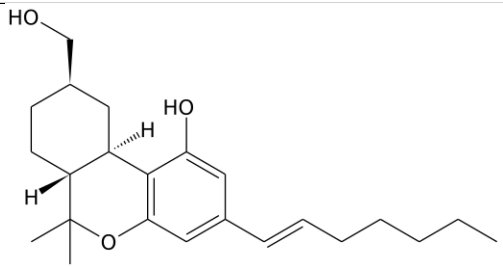
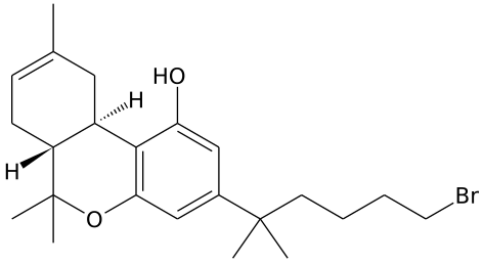
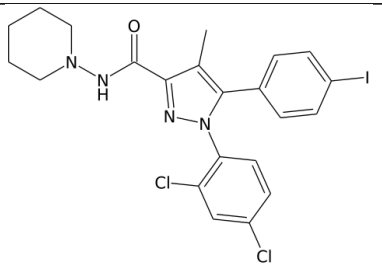
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10201	Fully Synthetic	CCH (C8)-CP 47,497	cannabicyclohexanol CP 47,497 dimethyloctyl homologue	$C_{22}H_{36}O_2$ 332.528 70434-92-3			
10202	Fully Synthetic	JWH-138		$C_{24}H_{36}O_2$ 356.55 431041-39-3			
10203	Fully Synthetic	AM-905		$C_{23}H_{34}O_3$ 358.522 181139-62-8			
10233	Fully Synthetic	AM-087		$C_{23}H_{33}BrO_2$ 421.419 152674-96-9			
10234	Fully Synthetic	AM-251		$C_{22}H_{21}Cl_2IN_4O$ 555.24 183232-66-8			

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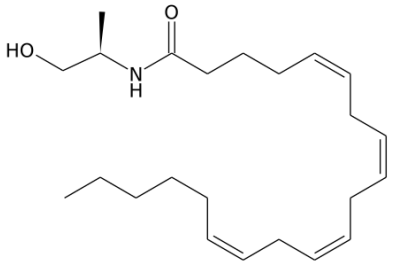
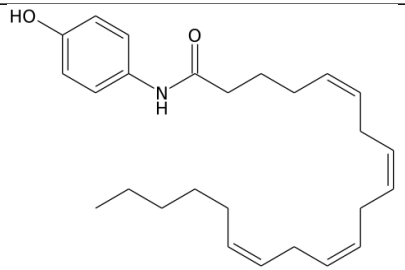
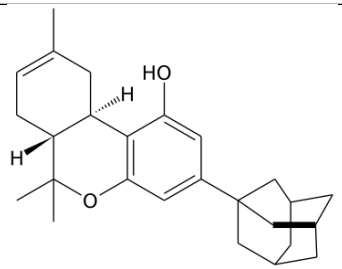
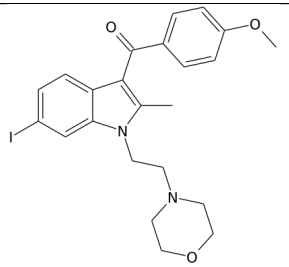
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10235	Fully Synthetic	AM-356	methanandamide	$C_{23}H_{39}NO_2$ 361.57 157182-49-5			
10236	Fully Synthetic	AM-404	N-arachidonoylphenolamine	$C_{26}H_{37}NO_2$ 395.587 198022-70-7			
10237	Fully Synthetic	AM-411		$C_{26}H_{34}O_2$ 378.556 5232865			
10238	Fully Synthetic	AM-603	6-Iodopravadoline	$C_{23}H_{25}IN_2O_3$ 504.368 164178-33-0			

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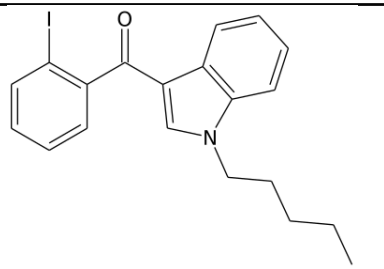
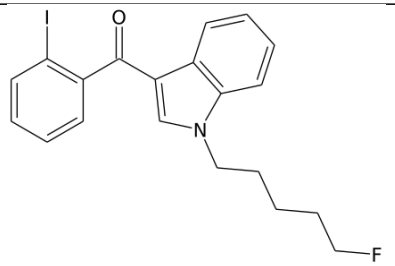
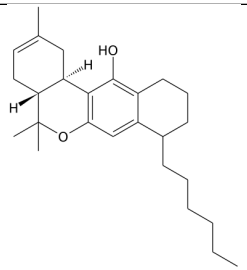
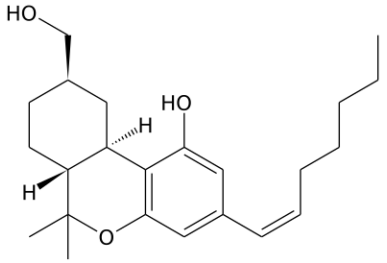
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10239	Fully Synthetic	AM-679		$C_{20}H_{20}INO$ 417.29 335160-91-3			
10240	Fully Synthetic	AM-694	1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole	$C_{20}H_{19}FINO$ 435.281 335161-03-0			
10241	Fully Synthetic	AM-855		$C_{26}H_{38}O_2$ 382.588 249888-50-4			
10242	Fully Synthetic	AM-906		$C_{23}H_{34}O_3$ 358.522 180989-26-8			

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Table 1 – continued from previous page

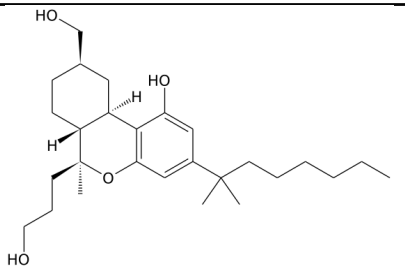
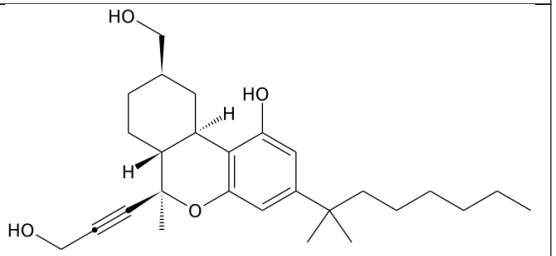
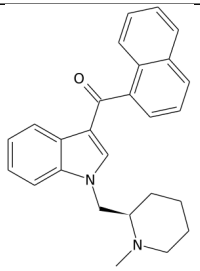
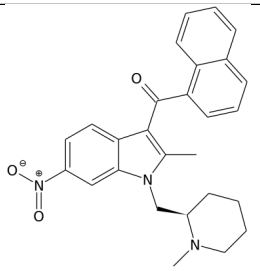
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10243	Fully Synthetic	AM-919		$C_{27}H_{44}O_4$ 432.645 164228-46-0			
10244	Fully Synthetic	AM-938		$C_{27}H_{40}O_4$ 428.613 303113-08-8			
10245	Fully Synthetic	AM-1220		$C_{26}H_{26}N_2O$ 382.507 134959-64-1			
10246	Fully Synthetic	AM-1221		$C_{27}H_{27}N_3O_3$ 441.531 335160-53-7			

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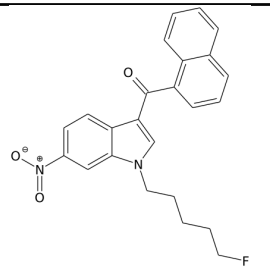
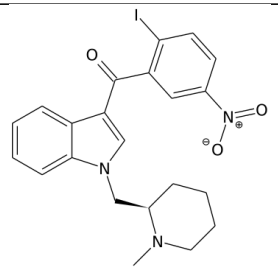
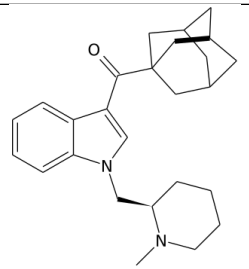
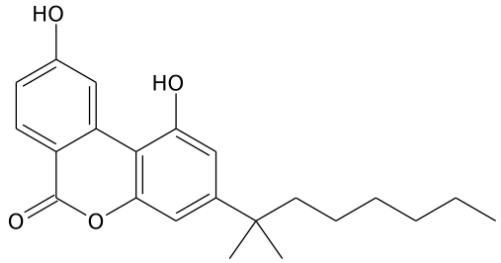
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10247	Fully Synthetic	AM-1235	1-(5-fluoropentyl)-3-(naphthalen-1-oyl)-6-nitroindole	$C_{24}H_{21}FN_2O_3$ 404.441 335161-27-8			
10248	Fully Synthetic	AM-1241	1-(methylpiperidin-2-ylmethyl)-3-(2-iodo-5-nitrobenzoyl)indole	$C_{22}H_{22}IN_3O_3$ 503.34 444912-48-5			
10249	Fully Synthetic	AM-1248		$C_{26}H_{34}N_2O$ 390.571 335160-66-2			
10250	Fully Synthetic	AM-1714		$C_{22}H_{26}O_4$ 354.446 335371-37-4			

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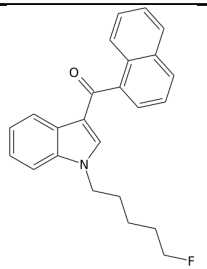
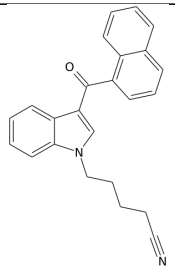
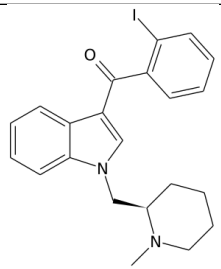
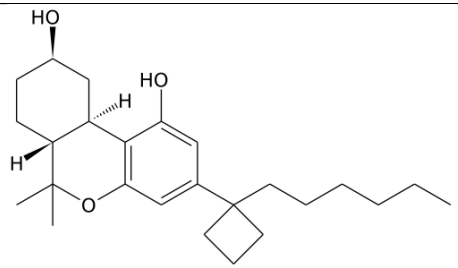
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10251	Fully Synthetic	AM-2201		$C_{24}H_{22}FNO$ 359.444 335161-24-5			
10252	Fully Synthetic	AM-2232		$C_{24}H_{20}N_2O$ 352.437 335161-19-8			
10253	Fully Synthetic	AM-2233		$C_{22}H_{23}IN_2O$ 458.343 444912-75-8			
10254	Fully Synthetic	AM-2389		$C_{25}H_{38}O_3$ 386.576 1256842-49-5			

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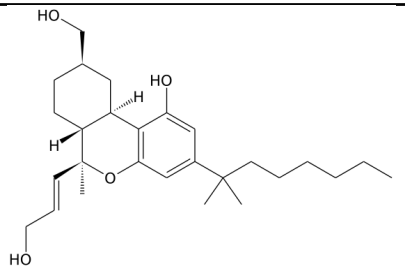
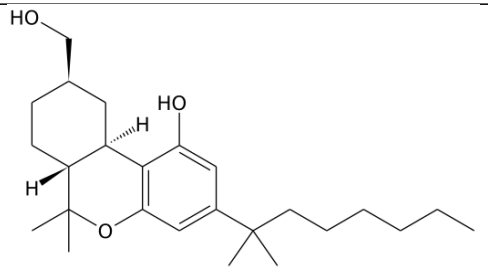
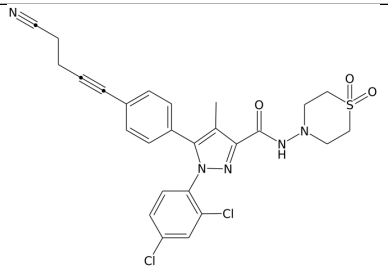
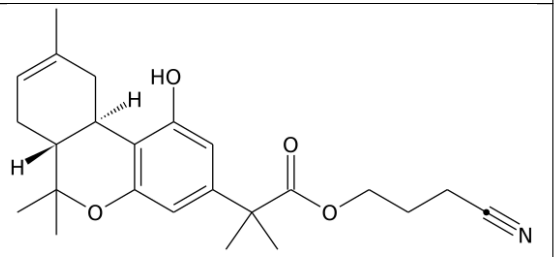
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10255	Fully Synthetic	AM-4030		$C_{27}H_{42}O_4$ 430.629 587023-54-9			
10256	Fully Synthetic	HU-243 AM-4056		$C_{25}H_{40}O_3$ 388.592 140835-18-3			
10257	Fully Synthetic	AM-6545		$C_{26}H_{23}Cl_2N_5O_3S$ 556.46 1245626-05-4			
10258	Fully Synthetic	AM-7438		$C_{24}H_{31}NO_4$ 397.515			

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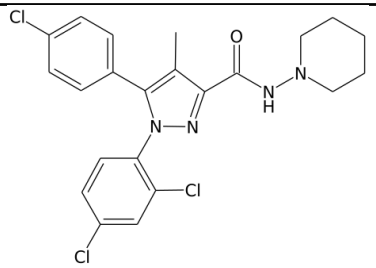
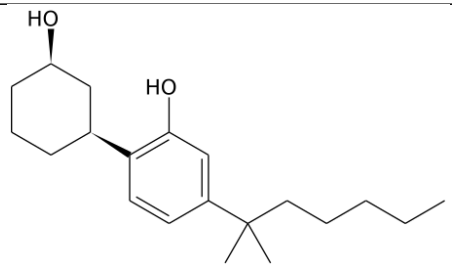
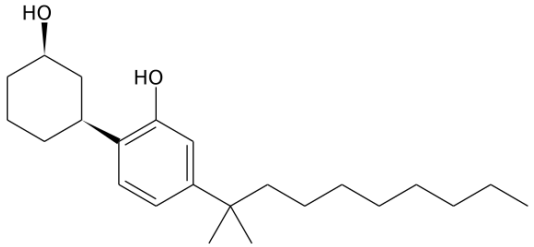
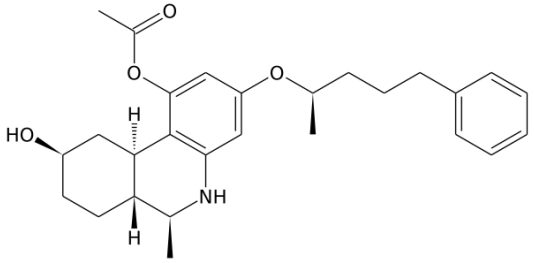
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10259	Fully Synthetic	SR141716	Rimonabant	$C_{22}H_{21}Cl_3N_4O$ 463.79 168273-06-1			
10260	Fully Synthetic	(C6)-CP 47,497		$C_{20}H_{32}O_2$ 304.474 132296-20-9			
10261	Fully Synthetic		C20H32O2	$C_{23}H_{38}O_2$ 346.555 134308-14-8			
10262	Fully Synthetic	CP 50,556-1	Levonantradol	$C_{27}H_{35}NO_4$ 437.58 71048-87-8			

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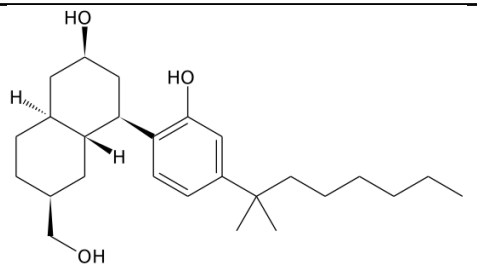
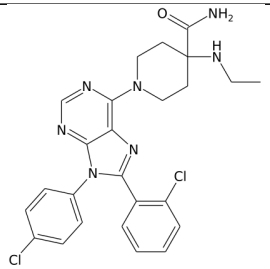
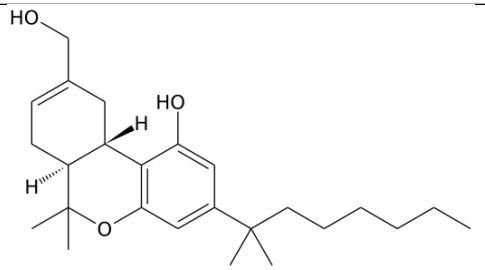
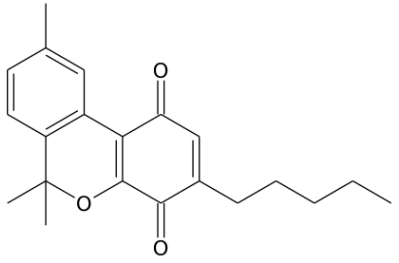
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10263	Fully Synthetic	CP 55,244		$C_{26}H_{42}O_3$ 402.619 79678-32-3			
10264	Fully Synthetic	CP-945,598	Otenabant	$C_{25}H_{25}Cl_2N_7O$ 510.42 686344-29-6			
10265	Fully Synthetic	HU-211 ETS2101	Dexanabinol	$C_{25}H_{38}O_3$ 386.576 112924-45-5			
10266	Fully Synthetic	HU-345		$C_{21}H_{24}O_3$ 324.42 731773-46-9			

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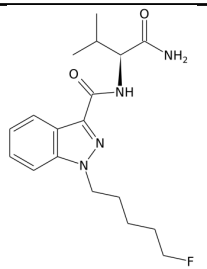
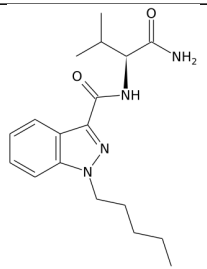
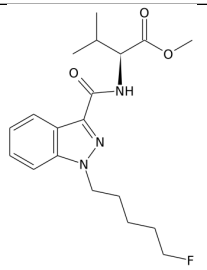
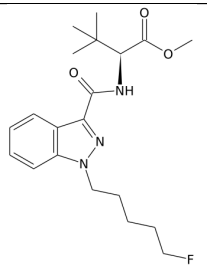
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10267	Fully Synthetic	5F-AB- PINACA		$C_{18}H_{25}FN_4O_2$ 348.422 1800101-60-3			
10268	Fully Synthetic	AB-PINACA		$C_{18}H_{26}N_4O_2$ 330.432 1445752-09-9			
10269	Fully Synthetic	5F-AMB 5F-MMB- PINACA 5F-AMB- PINACA		$C_{19}H_{26}FN_3O_3$ 363.433 1801552-03-3			
10270	Fully Synthetic	5F-ADB MDMB-5F- PINACA 5F-MDMB- PINACA		$C_{20}H_{28}FN_3O_3$ 377.46 1715016-75-3			

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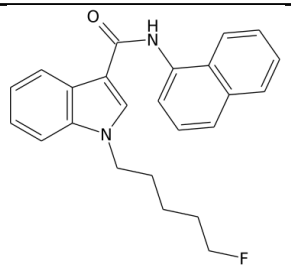
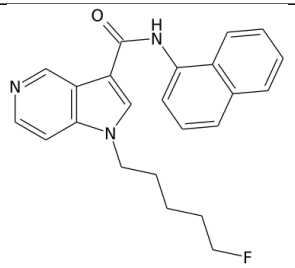
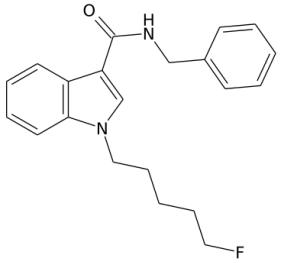
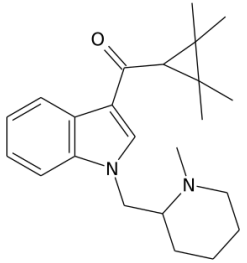
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10271	Fully Synthetic	5F-NNE1 5F-NNEI 5F-MN-24		$C_{24}H_{23}FN_2O$ 374.459 1445580-60-8			
10272	Fully Synthetic	5F-PCN 5F-MN-21		$C_{23}H_{22}FN_3O$ 375.447 2219332-48-4			
10273	Fully Synthetic	5F-SDB-006		$C_{21}H_{23}FN_2O$ 338.426 1776086-02-2			
10274	Fully Synthetic	AB-005		$C_{23}H_{32}N_2O$ 352.522 895155-25-6			

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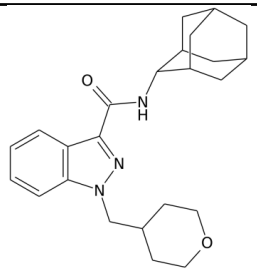
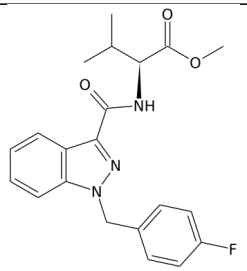
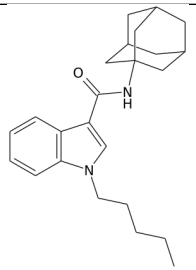
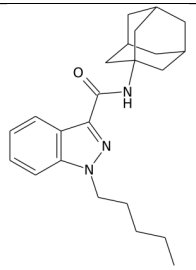
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10275	Fully Synthetic	ATHPINACA AD- THPINACA	Adamantyl-THPINACA	$C_{24}H_{31}N_3O_2$ 393.531 2365471-86-7			
10276	Fully Synthetic	AMB- FUBINACA FUB-AMB MMB- FUBINACA		$C_{21}H_{22}FN_3O_3$ 383.423 1971007-92-7			
10277	Fully Synthetic	APICA 2NE1 SDB-001	N-(1-adamantyl)-1- pentyl-1H-indole-3- carboxamide	$C_{24}H_{32}N_2O$ 364.533 1345973-50-3			
10278	Fully Synthetic	APINACA AKB48	N-(1-adamantyl)-1- pentyl-1H-indazole-3- carboxamide	$C_{23}H_{31}N_3O$ 365.521 1345973-53-6			

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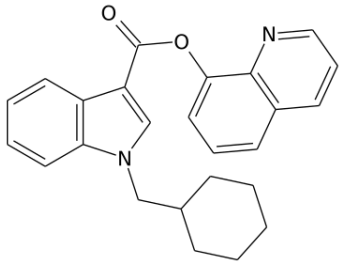
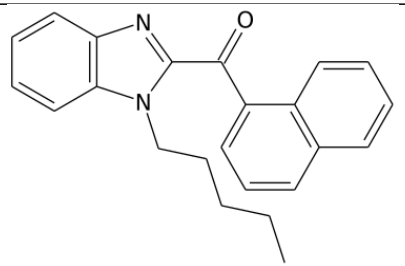
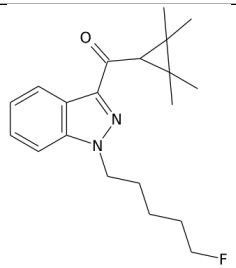
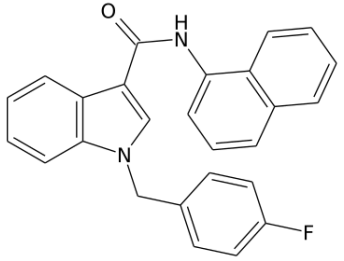
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10279	Fully Synthetic	QUCHIC BB-22 SGT-32	1-(cyclohexylmethyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester	$C_{25}H_{24}N_2O_2$ 384.479 1400742-42-8			
10280	Fully Synthetic	BIM-018		$C_{23}H_{22}N_2O$ 342.442 2316839-70-8			
10281	Fully Synthetic	FAB-144		$C_{20}H_{27}FN_2O$ 330.447 2180935-79-7			
10282	Fully Synthetic	FDU-NNE1 FDU-NNEI FDU-MN-24		$C_{26}H_{19}FN_2O$ 394.449 2365471-76-5			

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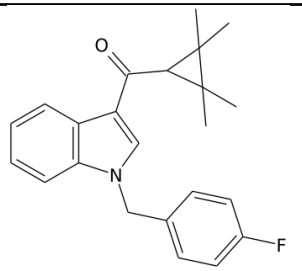
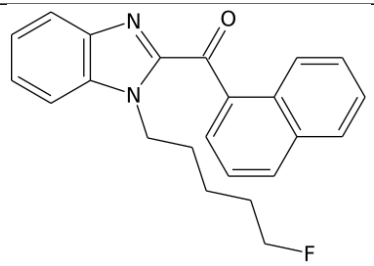
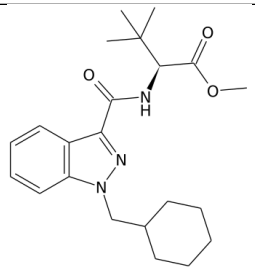
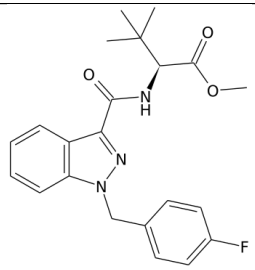
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10283	Fully Synthetic	FUB-144 FUB-UR-144		$C_{23}H_{24}FNO$ 349.449 2185863-15-2			
10284	Fully Synthetic	FUBIMINA BIM-2201 BZ-2201 FTHJ		$C_{23}H_{21}FN_2O$ 360.432 1984789-90-3			
10285	Fully Synthetic	MDMB-CHMICA		$C_{23}H_{32}N_2O_3$ 384.52 1971007-95-0			
10286	Fully Synthetic	MDMB-FUBINACA MDMB(N)-Bz-F FUB-MDMB		$C_{22}H_{24}FN_3O_3$ 397.45 1971007-93-8			

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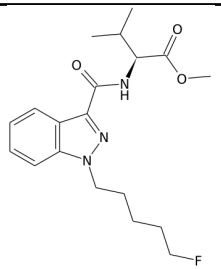
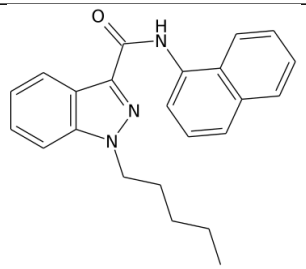
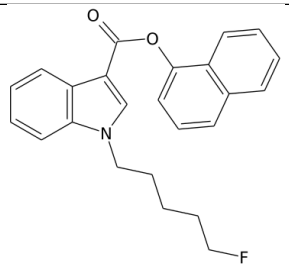
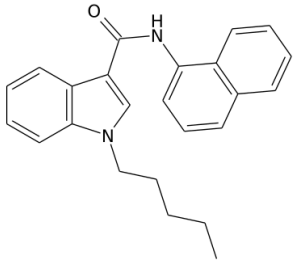
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10287	Fully Synthetic	MMB-2201 MMB-5F-PICA 5F-MMB-PICA 5F-AMB-PICA I-AMB		$C_{20}H_{27}FN_2O_3$ 362.445 1616253-26-9			
10288	Fully Synthetic	MN-18		$C_{23}H_{23}N_3O$ 357.457 1391484-80-2			
10289	Fully Synthetic	NM-2201 CBL-2201 NA-5F-PIC		$C_{24}H_{22}FNO_2$ 375.443 2042201-16-9			
10290	Fully Synthetic	NNE1 NNEI MN-24 AM-6527		$C_{24}H_{24}N_2O$ 356.469 1338925-11-3			

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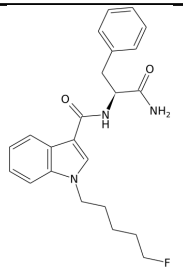
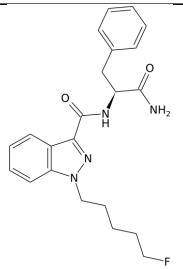
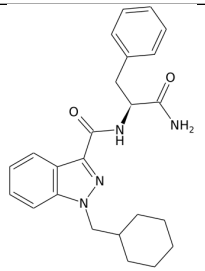
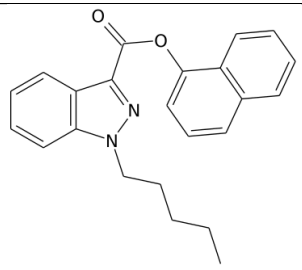
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10291	Fully Synthetic	PX-1 5F-APP-PICA SRF-30		$C_{23}H_{26}FN_3O_2$ 395.478 2221100-71-4			
10292	Fully Synthetic	PX-2 5F-APP-PINACA FU-PX PPA(N)-2201		$C_{22}H_{25}FN_4O_2$ 396.466 2365471-47-0			
10293	Fully Synthetic	PX-3 APP-CHMINACA		$C_{24}H_{28}N_4O_2$ 404.514 1185887-14-2			
10294	Fully Synthetic	SDB-005		$C_{23}H_{22}N_2O_2$ 358.441 2180934-13-6			

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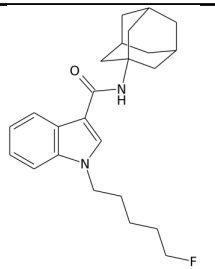
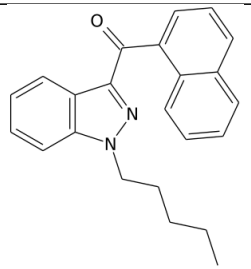
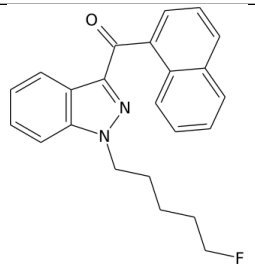
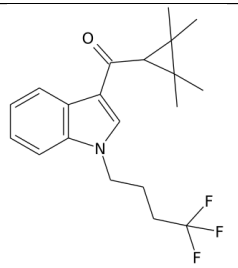
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10295	Fully Synthetic	STS-135 5F-APICA	N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide	$C_{24}H_{31}FN_2O$ 382.523 1354631-26-7			
10296	Fully Synthetic	THJ-018 SGT-17		$C_{23}H_{22}N_2O$ 342.442 1364933-55-0			
10297	Fully Synthetic	THJ-2201		$C_{23}H_{21}FN_2O$ 360.432 1801552-01-1			
10298	Fully Synthetic	XLR-12		$C_{20}H_{24}F_3NO$ 351.413 895155-78-9			

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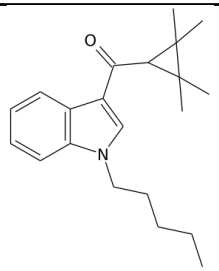
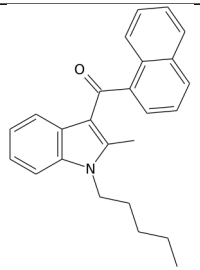
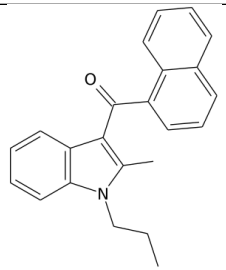
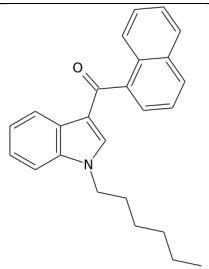
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10299	Fully Synthetic	UR-144 TMCP-018 KM-X1 MN-001 YX-17		$C_{21}H_{29}NO$ 311.469 1199943-44-6			
10300	Fully Synthetic	JWH-007		$C_{25}H_{25}NO$ 355.481 8217871			
10301	Fully Synthetic	JWH-015		$C_{23}H_{21}NO$ 327.427 8217806			
10302	Fully Synthetic	JWH-019		$C_{25}H_{25}NO$ 355.481 3983552			

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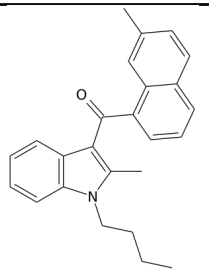
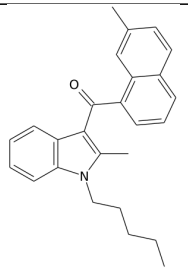
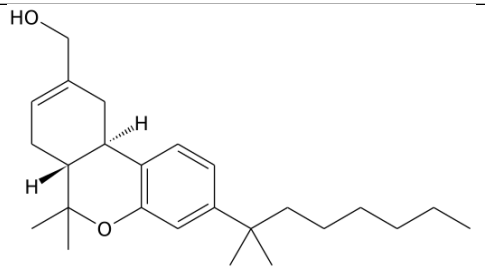
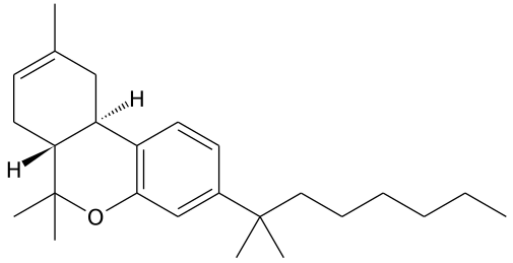
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10303	Fully Synthetic	JWH-047		$C_{25}H_{25}NO$ 355.481 316189-65-8			
10304	Fully Synthetic	JWH-048		$C_{26}H_{27}NO$ 369.508 316189-66-9			
10305	Fully Synthetic	JWH-051		$C_{25}H_{38}O_2$ 370.577			
10306	Fully Synthetic	JWH-057		$C_{25}H_{38}O$ 354.578 105823-04-9			

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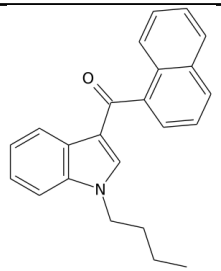
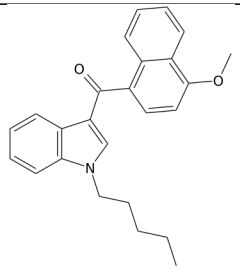
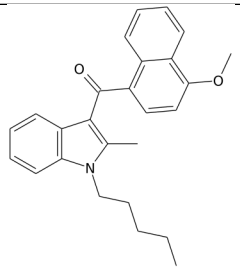
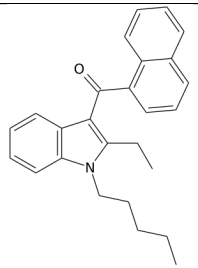
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10307	Fully Synthetic	JWH-073		$C_{23}H_{21}NO$ 327.427 208987-48-8			
10308	Fully Synthetic	JWH-081		$C_{25}H_{25}NO_2$ 371.48 210179-46-7			
10309	Fully Synthetic	JWH-098		$C_{26}H_{27}NO_2$ 385.507 316189-74-9			
10310	Fully Synthetic	JWH-116		$C_{26}H_{27}NO$ 369.508 619294-64-3			

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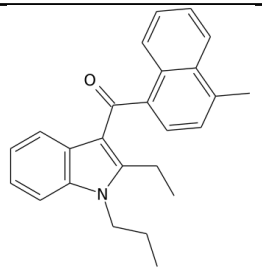
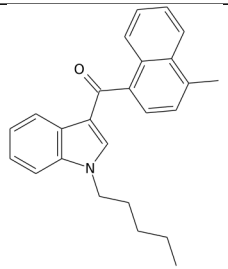
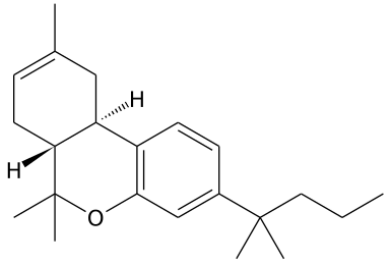
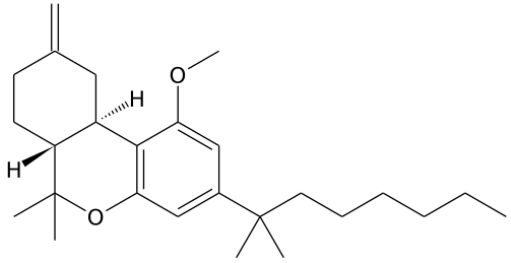
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10311	Fully Synthetic	JWH-120		$C_{23}H_{21}NO$ 327.427 824955-98-8			
10312	Fully Synthetic	JWH-122		$C_{25}H_{25}NO$ 355.481 619294-47-2			
10313	Fully Synthetic	JWH-133	Dimethylbutyl-deoxy- Delta-8-THC	$C_{22}H_{32}O$ 312.497 259869-55-1			
10314	Fully Synthetic	JWH-142 L-759,656		$C_{26}H_{40}O_2$ 384.604 174627-56-6			

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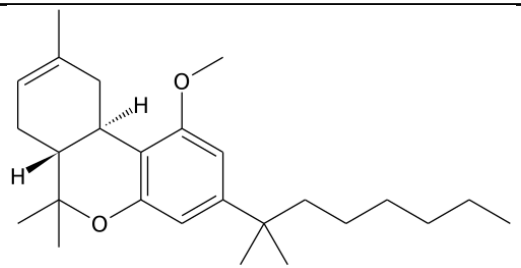
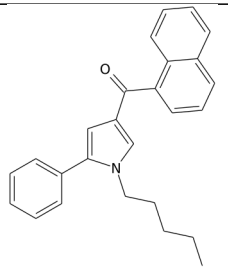
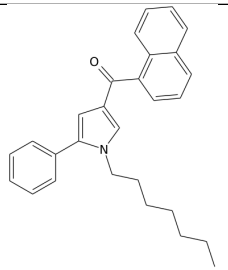
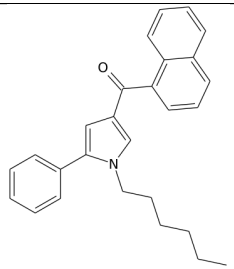
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10315	Fully Synthetic	JWH-143 L-759,633		$C_{26}H_{40}O_2$ 384.604 174627-50-0			
10316	Fully Synthetic	JWH-145		$C_{26}H_{25}NO$ 367.492 914458-19-8			
10317	Fully Synthetic	JWH-146	1-heptyl-5-phenyl- 1H-pyrrol-3-yl)-1- naphthalenyl-methanone	$C_{28}H_{29}NO$ 395.546 914458-21-2			
10318	Fully Synthetic	JWH-147		$C_{27}H_{27}NO$ 381.519 914458-20-1			

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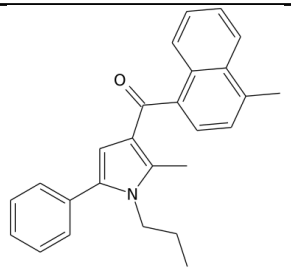
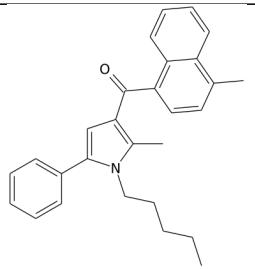
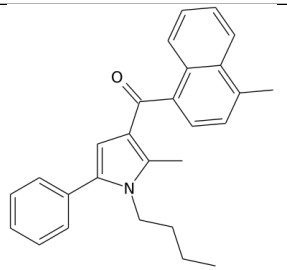
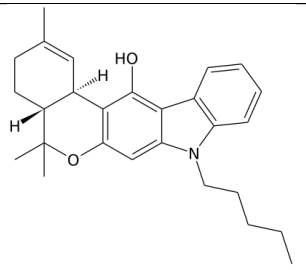
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10319	Fully Synthetic	JWH-148		$C_{24}H_{23}NO$ 341.454 824955-99-9			
10320	Fully Synthetic	JWH-149		$C_{26}H_{27}NO$ 369.508 548461-82-1			
10321	Fully Synthetic	JWH-150	(1-butyl-5-phenylpyrrol-3-yl)-naphthalen-1-ylmethanone	$C_{25}H_{23}NO$ 353.465 914458-18-7			
10322	Fully Synthetic	JWH-161		$C_{27}H_{33}NO_2$ 403.566			

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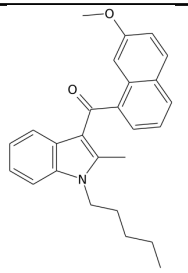
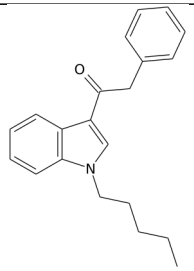
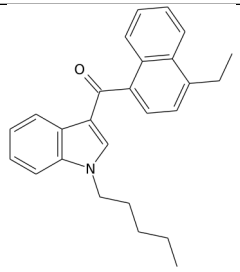
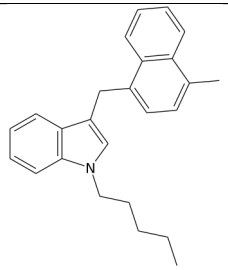
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10323	Fully Synthetic	JWH-164		$C_{25}H_{25}NO_2$ 371.48 824961-61-7			
10324	Fully Synthetic	JWH-167	1-pentyl-3-(phenylacetyl)indole	$C_{21}H_{23}NO$ 305.421 864445-37-4			
10325	Fully Synthetic	JWH-210		$C_{26}H_{27}NO$ 369.508 824959-81-1			
10326	Fully Synthetic	JWH-184		$C_{25}H_{27}N$ 341.498 619294-37-0			

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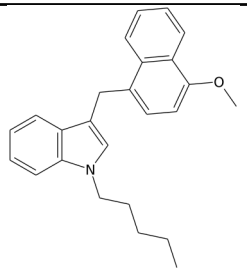
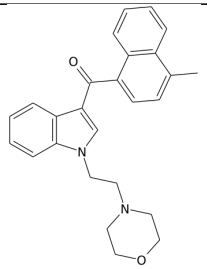
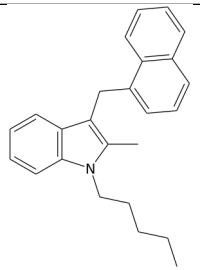
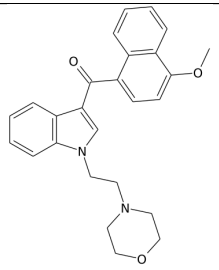
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10327	Fully Synthetic	JWH-185		$C_{25}H_{27}NO$ 357.497 619294-39-2			
10328	Fully Synthetic	JWH-193		$C_{26}H_{26}N_2O_2$ 398.506 133438-58-1			
10329	Fully Synthetic	JWH-196		$C_{25}H_{27}N$ 341.498 619294-41-6			
10330	Fully Synthetic	JWH-198		$C_{26}H_{26}N_2O_3$ 414.505 166599-76-4			

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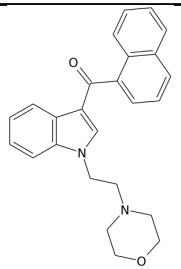
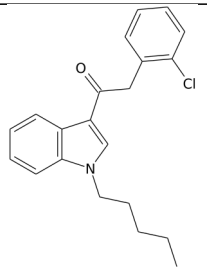
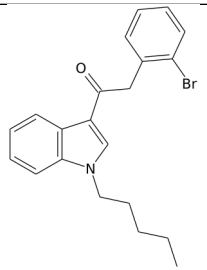
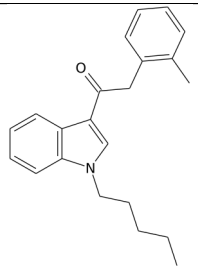
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10331	Fully Synthetic	JWH-200		$C_{25}H_{24}N_2O_2$ 384.479 103610-04-4			
10332	Fully Synthetic	JWH-203		$C_{21}H_{22}ClNO$ 339.86 864445-54-5			
10333	Fully Synthetic	JWH-249		$C_{21}H_{22}BrNO$ 384.317 864445-60-3			
10334	Fully Synthetic	JWH-251		$C_{22}H_{25}NO$ 319.448 864445-39-6			

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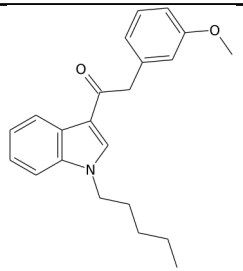
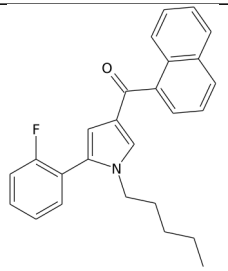
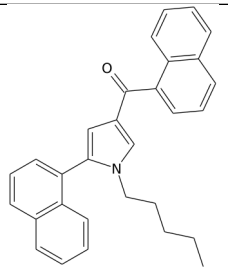
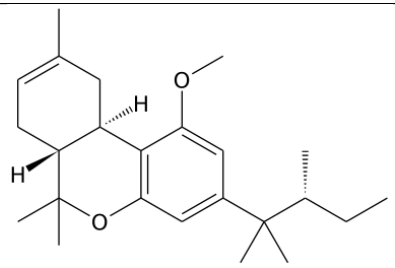
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10335	Fully Synthetic	JWH-302		$C_{22}H_{25}NO_2$ 335.447 864445-45-4			
10336	Fully Synthetic	JWH-307		$C_{26}H_{24}FNO$ 385.482 914458-26-7			
10337	Fully Synthetic	JWH-309		$C_{30}H_{27}NO$ 417.552 914458-42-7			
10338	Fully Synthetic	JWH-359		$C_{24}H_{36}O_2$ 356.55			

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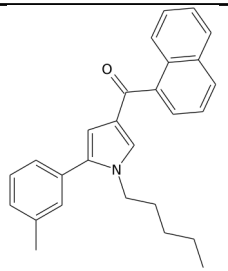
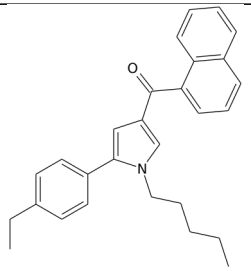
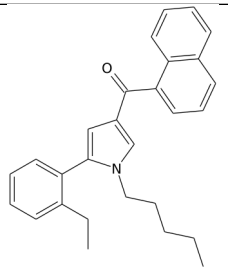
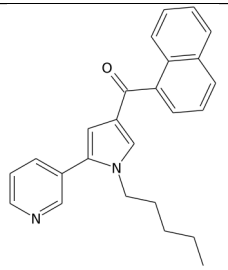
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10339	Fully Synthetic	JWH-363		$C_{27}H_{24}F_3NO$ 435.49 914458-33-6			
10340	Fully Synthetic	JWH-364		$C_{28}H_{29}NO$ 395.546 914458-36-9			
10341	Fully Synthetic	JWH-365		$C_{28}H_{29}NO$ 395.546 914458-23-4			
10342	Fully Synthetic	JWH-366		$C_{25}H_{24}N_2O$ 368.48 914458-44-9			

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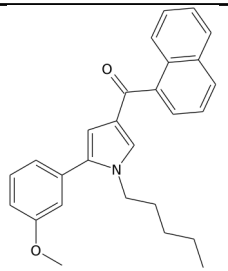
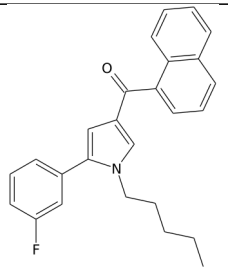
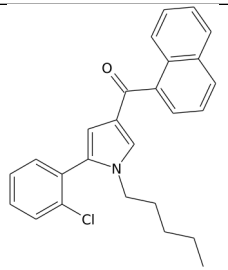
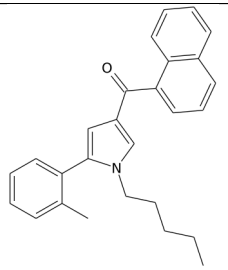
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10343	Fully Synthetic	JWH-367		$C_{27}H_{27}NO_2$ 397.518 914458-30-3			
10344	Fully Synthetic	JWH-368		$C_{26}H_{24}FNO$ 385.482 914458-31-4			
10345	Fully Synthetic	JWH-369		$C_{26}H_{24}ClNO$ 401.93 914458-27-8			
10346	Fully Synthetic	JWH-370		$C_{27}H_{27}NO$ 381.519 914458-22-3			

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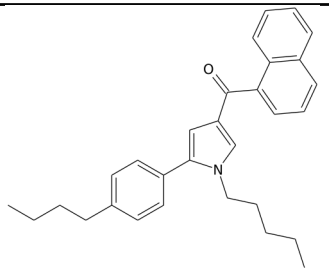
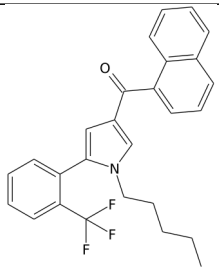
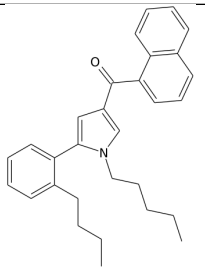
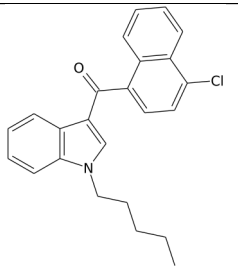
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10347	Fully Synthetic	JWH-371		$C_{30}H_{33}NO$ 423.6			
10348	Fully Synthetic	JWH-372		$C_{27}H_{24}F_3NO$ 435.49 914458-28-9			
10349	Fully Synthetic	JWH-373		$C_{30}H_{33}NO$ 423.6 914458-37-0			
10350	Fully Synthetic	JWH-398		$C_{24}H_{22}ClNO$ 375.9 1292765-18-4			

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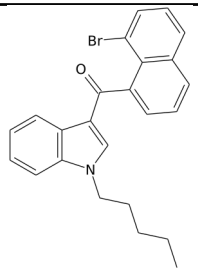
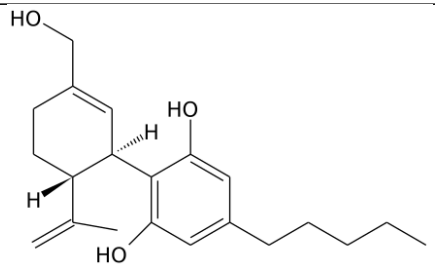
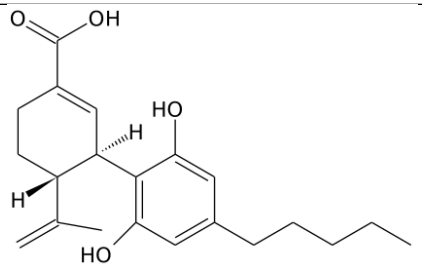
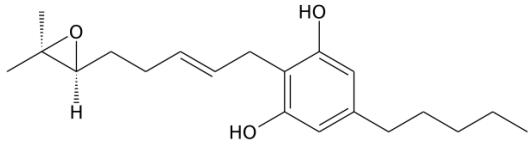
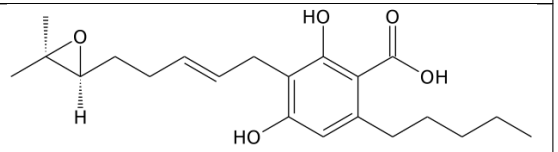
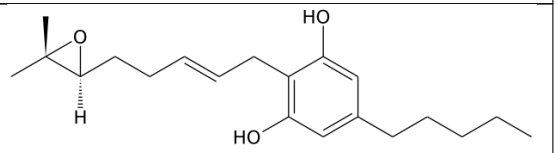
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10351	Fully Synthetic	JWH-424		$C_{24}H_{22}BrNO$ 420.35 1366068-04-3			
10137	Metabolite	7-OH-CBD	7-Hydroxycannabidiol	$C_{21}H_{30}O_3$ 330.468 50725-17-2			
10190	Metabolite	7-COOH-CBD 7-nor-1-COOH-CBD	7-carboxycannabidiol 7-nor-1-carboxycannabidiol	$C_{21}H_{28}O_4$ 344.199			
10117	Metabolite	(a)-6,7-cis-epoxy-CBG	(α)-6,7-cis-epoxycannabigerol	$C_{21}H_{32}O_3$ 332.5 140381-46-0			
10118	Metabolite	(a)-6,7-cis-epoxy-CBGA	(α)-6,7-cis-epoxycannabigerolic acid	$C_{22}H_{32}O_5$ 376.225 140381-46-0			
10119	Metabolite	(a)-6,7-trans-epoxy-CBG	(α)-6,7-trans-epoxycannabigerol	$C_{21}H_{32}O_3$ 332.5 140381-46-0			

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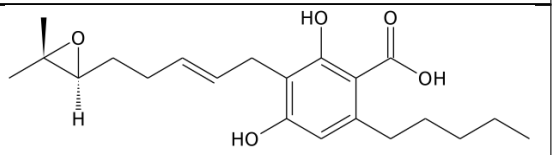
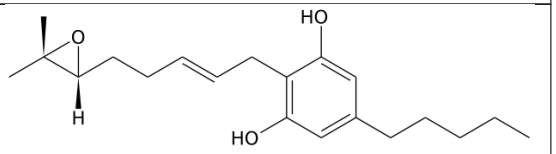
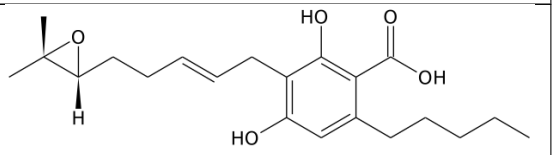
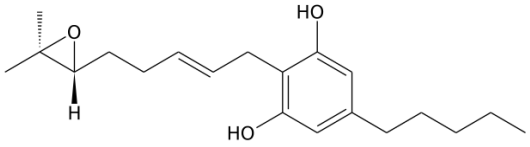
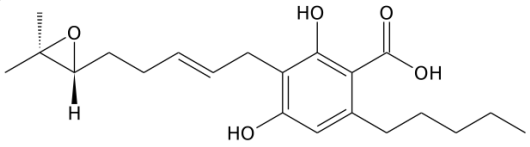
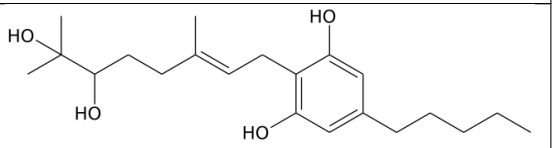
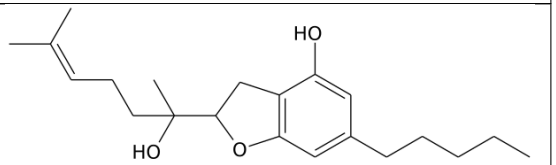
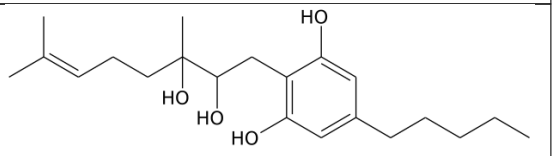
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10120	Metabolite	(a)-6,7-trans-epoxy-CBGA	(α)-6,7-trans-epoxycannabigerolic acid	$C_{22}H_{32}O_5$ 376.225 140381-46-0			
10126	Metabolite	(b)-6,7-cis-epoxy-CBG	(β)-6,7-cis-epoxycannabigerol	$C_{21}H_{32}O_3$ 332.5 140381-46-0			
10127	Metabolite	(b)-6,7-cis-epoxy-CBGA	(β)-6,7-cis-epoxycannabigerolic acid	$C_{22}H_{32}O_5$ 376.225 140381-46-0			
10128	Metabolite	(b)-6,7-trans-epoxy-CBG	(β)-6,7-trans-epoxycannabigerol	$C_{21}H_{32}O_3$ 332.5 140381-46-0			
10129	Metabolite	(b)-6,7-trans-epoxy-CBGA	(β)-6,7-trans-epoxycannabigerolic acid	$C_{22}H_{32}O_5$ 376.225 140381-46-0			
10150	Metabolite	6,7-di-OH-CBG	Carmagerol 6,7-dihydroxycannabigerol	$C_{21}H_{34}O_4$ 350.246 140396-81-2			
10189	Metabolite	Cyclo-CBG	cyclocannabigerol	$C_{21}H_{32}O_3$ 332.5			
10192	Metabolite	2,3-di-OH-CBG	2,3-dihydroxycannabigerol	$C_{21}H_{32}O_4$ 348.23			

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Table 1 – continued from previous page

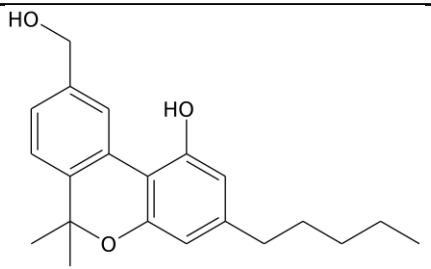
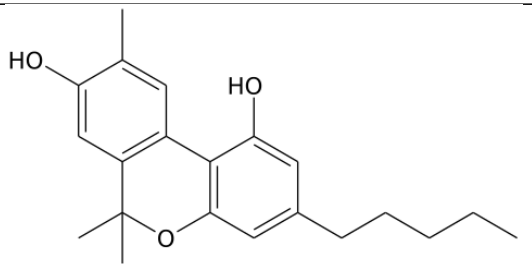
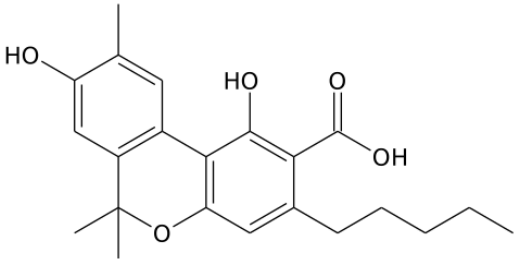
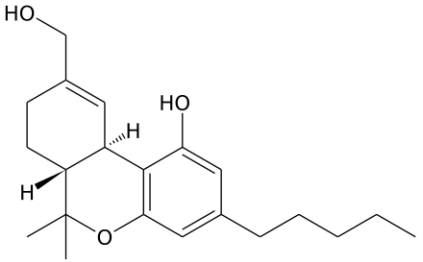
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10134	Metabolite	11-OH-CBN	11-Hydroxycannabinol	$C_{21}H_{26}O_3$ 326.436 10421320			
10138	Metabolite	8-OH-CBN	8-hydroxy-cannabinol	$C_{21}H_{26}O_3$ 326.188			
10139	Metabolite	8-OH-CBNA	8-hydroxy-cannabinolic acid	$C_{22}H_{26}O_5$ 370.178			
10132	Metabolite	11-OH-THC	11-hydroxy-tetrahydrocannabinol	$C_{21}H_{30}O_3$ 330.464 36557-05-8			

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Table 1 – continued from previous page

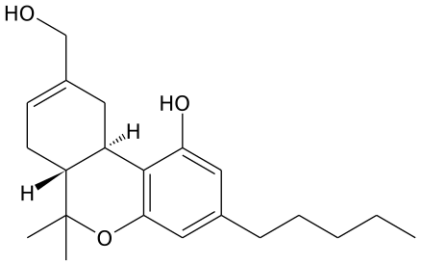
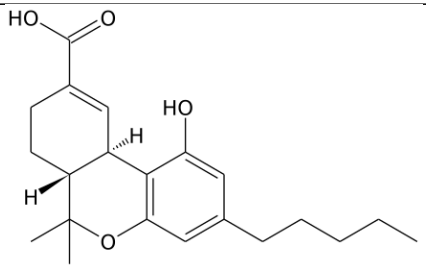
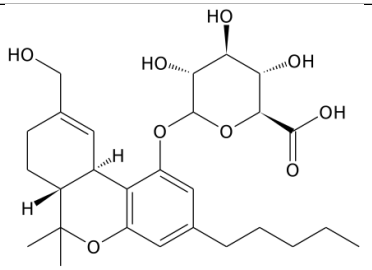
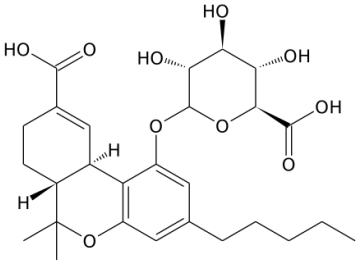
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10133	Metabolite	11-OH-d8-THC	11-Hydroxy-Δ-8-tetrahydrocannabinol	$C_{21}H_{30}O_3$ 330.468 28646-40-4			
10136	Metabolite	11-nor-9-COOH-THC	11-nor-9-Carboxy-tetrahydrocannabinol	$C_{21}H_{28}O_4$ 344.448 56354-06-4			
10151	Metabolite	Gluc-11-OH-THC	Glucuronidated-11-hydroxy-tetrahydrocannabinol	$C_{27}H_{38}O_9$ 560.59			
10152	Metabolite	Gluc-11-nor-9-COOH-THC	Glucuronidated-11-nor-9-Carboxy-tetrahydrocannabinol	$C_{27}H_{36}O_{10}$ 520.573			

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Table 1 – continued from previous page

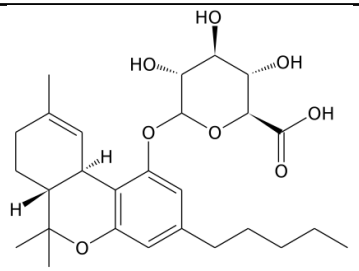
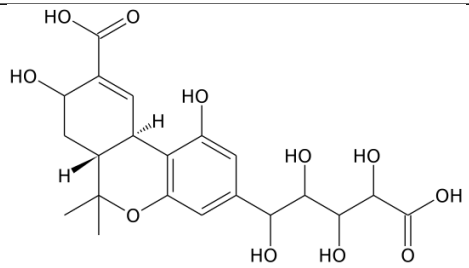
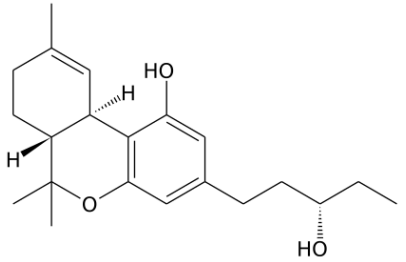
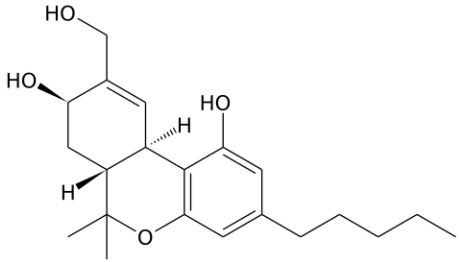
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10153	Metabolite	Gluc-THC	Glucuronidated-tetrahydrocannabinol	$C_{27}H_{38}O_8$ 490.59			
10154	Metabolite	Poly-OH-5'-11-COOH-THC	Poly-hydroxy-5'-11-COhydroxy-tetrahydrocannabinol	$C_{21}H_{26}O_{11}$ 454.428			
10193	Metabolite	3'-OH-THC	3'-hydroxytetrahydrocannabinol	$C_{21}H_{30}O_3$ 330.468 58434-44-9			
10194	Metabolite	8,11-di-OH-THC	8,11-dihydroxytetrahydrocannabinol	$C_{21}H_{30}O_4$ 346.214			

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Table 1 – continued from previous page

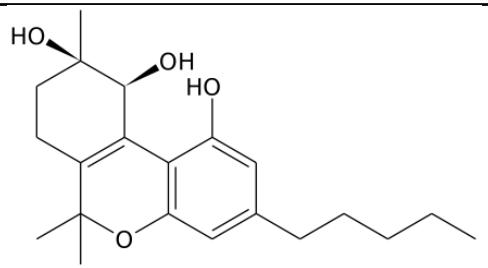
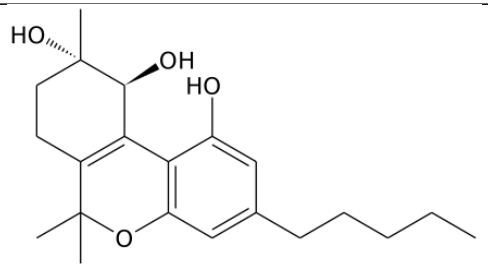
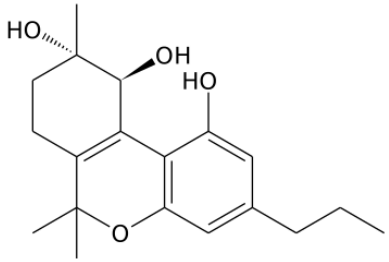
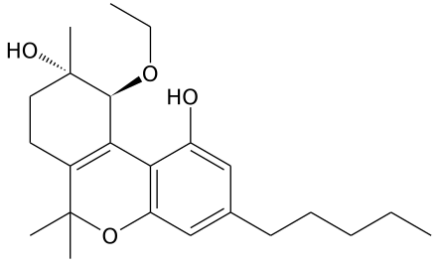
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10121	Metabolite	(a)-cis-CBT	(α)-cis-cannabitriol	$C_{21}H_{30}O_4$ 346.467			
10122	Metabolite	(a)-trans-CBT	(α)-trans-cannabitriol	$C_{21}H_{30}O_4$ 346.467			
10123	Metabolite	(a)-trans-CBTV	(α)-trans-cannabitrivarin	$C_{19}H_{26}O_4$ 318.183			
10124	Metabolite	(a)-trans-OEt-CBT	(α)-trans-ethoxycannabitriol	$C_{23}H_{34}O_4$ 374.517			

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Table 1 – continued from previous page

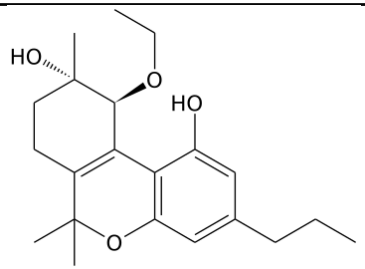
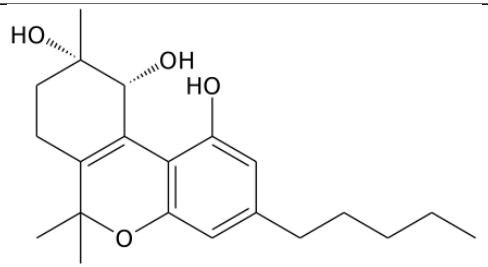
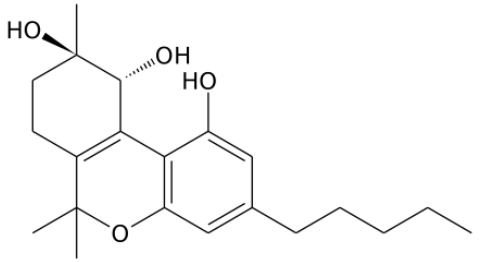
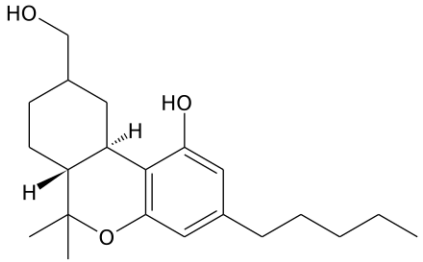
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10125	Metabolite	(a)-trans-OEt-CBT-C3 (a)-trans-OEt-CBTV	(α)-trans-ethoxycannabitriol-C3 homologue (α)-trans-ethoxycannabitrivarin	$C_{21}H_{30}O_4$ 346.464			
10130	Metabolite	(b)-cis-CBT	(β)-cis-cannabitriol	$C_{21}H_{30}O_4$ 346.467			
10131	Metabolite	(b)-trans-CBT	(β)-trans-cannabitriol	$C_{21}H_{30}O_4$ 346.467			
10135	Metabolite	11-OH-HHC	11-Hydroxyhexahydrocannabinol	$C_{21}H_{32}O_3$ 332.484 64663-39-4			

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Table 1 – continued from previous page

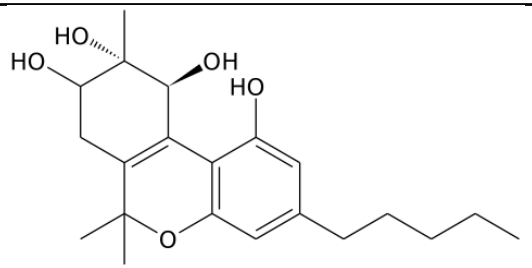
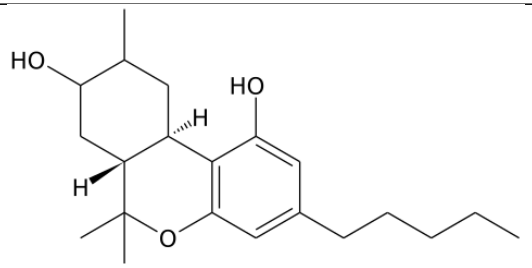
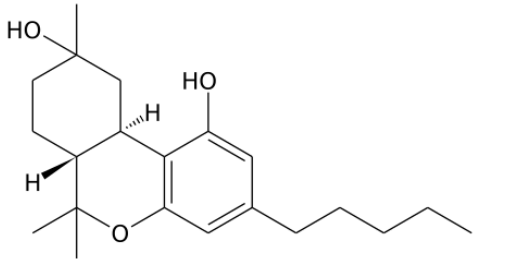
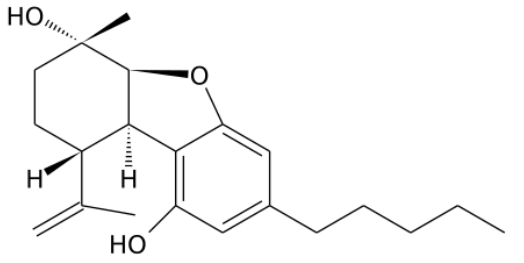
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10140	Metabolite	8-OH-CBT	8-hydroxy-cannabitriol	$C_{21}H_{30}O_5$ 362.209			
10141	Metabolite	8-OH-HHC	8-Hydroxyhexahydrocannabinol	$C_{21}H_{32}O_3$ 332.484 36403-92-6			
10142	Metabolite	9-OH-HHC	9-Hydroxyhexahydrocannabinol	$C_{21}H_{32}O_3$ 332.484 36028-45-2			
10143	Metabolite	CBE	cannabielsoin	$C_{21}H_{30}O_3$ 330.468 52025-76-0			

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Table 1 – continued from previous page

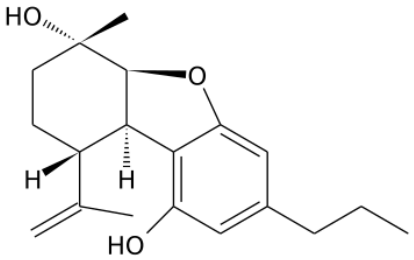
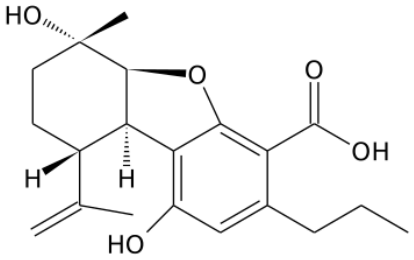
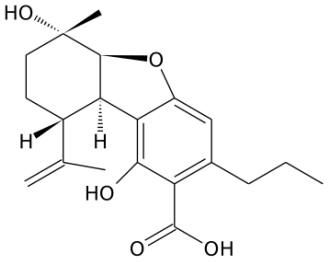
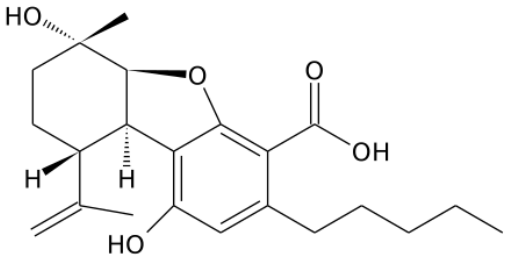
ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10144	Metabolite	CBEV CBE-C3	Cannabielsoin-C3 homoglue Cannabielsovarin	$C_{20}H_{26}O_3$ 314.188			
10145	Metabolite	CBEVA-A	Cannabielsoinic acid A-C3 homoglue	$C_{21}H_{26}O_5$ 358.178			
10146	Metabolite	CBEVA-B	Cannabielsoinic acid B-C3 homoglue	$C_{21}H_{26}O_5$ 358.178			
10147	Metabolite	CBEA-A	cannabielsoinlic acid-A	$C_{22}H_{30}O_5$ 374.209 9048552			

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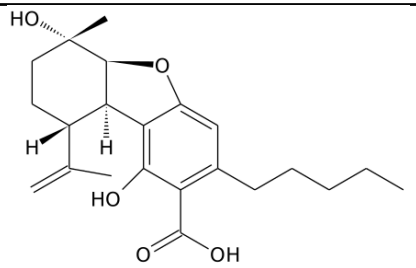
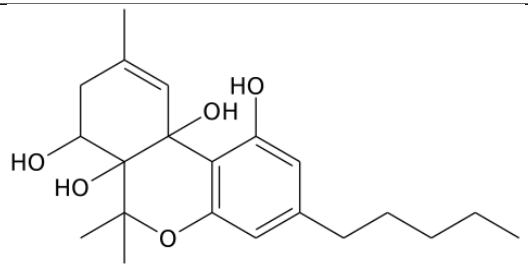
Table 1 – continued from previous page

ID	Source	Name1 Acronym	Name2 Full-Name	Formula Mass CAS No.	BNK1	BNK2	Image
10148	Metabolite	CBEA-B	cannabielsoinlic acid-B	$C_{22}H_{30}O_5$ 374.209 55652-62-5			
10149	Metabolite	CBTT	cannabitetrol	$C_{21}H_{30}O_5$ 362.463			

THIRD PARTY LABORATORY QUALIFICATION SELF-AUDIT

Third Party Laboratory
Address:
Contact:
Phone:
Email:
Date:

I. Basic Information

- Please list all analyses performed in the lab.
- For each analysis, please provide the following:
    - Instruments and methods
    - List of analytes
    - LOD, LOQ, Reporting Limits
    - How often are blank, standards, and spiked matrix samples analyzed?
    - How often are facilities tested for possible analyte contamination?

II. Documentation

Please provide copies of the following:

- Index of Standard Operating Procedures
- Company Organizational Chart
- Equipment List
- Accreditations and Certifications

III. Qualifications

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. Has management defined, documented, and communicated its Quality Policy to its organization?
2. Has management appointed quality responsibility and authority to appropriate personnel?
3. Does the lab have a documented Quality System?
4. Does the management regularly review the Quality System at scheduled intervals?
5. Does the lab have a quality manual approved by management?
6. Are quality reports issued to management and used as a basis for continual improvement?
7. What accreditations does the laboratory maintain? Please list and attach copies.
8. Is there an SOP for sample submittal and receiving?
9. Is each sample assigned a unique laboratory identification number? How is it assigned?
10. Are samples stored securely and labeled with proper identity?
11. Is there a log of stored samples? For how long are samples stored?
12. Are temperature and humidity of sample storage area recorded?
13. Is a Certificate of Analysis (CofA) issued for each test performed?

14. Is all data on CofA's traceable to raw data stored by the laboratory?
15. How are CofA's for each customer stored? For how long?
16. Are clients notified of any method deviations taken during analysis? Is there a system for obtaining customer agreement to these changes?
17. Are there procedures to control, revise, and change documents?
18. Are all appropriate documents controlled and identified by revision level or date?
19. Do authorized personnel approve controlled documents prior to issue?
20. Are there SOP's available for handling reference standards and working standards?
21. Are CofAs and/or reference data for these standards available?
22. Are storage data and conditions available for these standards?
23. How often are standards re-analyzed or re-certified?
24. Do you have SOPs or guidelines on continual improvement?
25. Are SOPs and manuals available for handling all instruments?
26. Does the laboratory have a subcontractor list and approval system?
27. Does the laboratory conduct subcontractor audits? How often?
28. Are all reagents and chemicals sourced from approved suppliers?
29. Are reference standards certified (NIST or other)?
30. Are all reagents and chemicals marked with date of receipt, date opened, and expiration date? How are expiration dates assigned?
31. Does the laboratory have a documented calibration system?
32. Are there SOP's for calibration?
33. When calibration are performed by an outside contractor, does the laboratory require certifications and test data?
34. Are all calibrations traceable to NIST?
35. Are all analytical methods validated?
36. Are analytical method validation test data available?
37. Are all instruments currently certified to perform within the scope required for each analysis?
38. Are instruments calibrated? What is the calibration schedule?
39. Are weights used certified?
40. Is calibration data available for verification?
41. What are the procedures for re-testing a sample?
42. Are test results / chromatograms signed and dated by the analyst?
43. Is there a log for each instrument and piece of equipment? Is the log up to date?
44. Are laminar air flow stations validated for: velocity, filter integrity, linearity? How often?
45. Are records kept of temperature / pressure of each autoclave run?
46. Have you done heat distribution studies on the autoclave?
47. Are there SOP's for destruction of samples, media, and reagents?
48. Does the laboratory perform internal quality audits to verify that departmental personnel comply with established procedures?
49. Are follow-up audits performed in the case of any corrective action findings?
50. Are records of internal audits available?
51. Is there an SOP for observations that are outside of operating specifications?
52. Do you have an SOP for guidelines on Good Laboratory Practices (GLP)?
53. Are training records on each SOP available?
54. Is a training assessment of each analyst complete and certified?

LABORATORY QUALIFICATION SELF-AUDIT

INSTRUCTIONS:

This laboratory qualification self-audit is intended to aid a laboratory's clients in requesting the proper information to asses the quality of scientific results being reported by the laboratory to the client. An audit allows both the client and the laboratory a formal and well-documented procedure to examine and validate the accuracy and reliability of the laboratory results reported to the client.

This procedure is initiated by the client and completed by the laboratory. The client fills out the client information, the date of the audit request, and the sections of the audit requested. The laboratory then receives this document, fills out the appropriate laboratory information, the date the audit is returned to the client, and the sections that for which answers were provided.

The laboratory can provide the answers to the question on a separate sheet and or document, and return it to the client enclosed with the original completed audit form. For simplicity of tracking, we ask that lab responses follow the numbering scheme adopted in the audit questionnaire. Copies should be kept by the laboratory for its own records.

Client Company Name					
-Client Point of Contact					
-Client Phone Number					
-Client Address					
-Client Email					
Client Date Requested					
Sections Requested	I.	II.	III.	IV.	V.

Laboratory Name					
-Lab Point of Contact					
-Lab Phone Number					
-Lab Address					
-Lab Email					
Lab Date Returned					
Sections Provided	I.	II.	III.	IV.	V.

I. Basic Information

1. Please list all analyses performed in the lab.
2. For each analysis, please provide the following:
   A. Instruments and methods
   B. List of analytes
   C. LOD, LOQ, Reporting Limits
   D. How often are blank, standards, and spiked matrix samples analyzed?
   E. How often are facilities tested for possible analyte contamination?

II. Documentation

Please provide copies of the following:

1. Index of Standard Operating Procedures
2. Company Organizational Chart
3. Equipment List
4. Accreditations and Certifications

III. General Qualifications

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. Has management defined, documented, and communicated its Quality Policy to its organization?
2. Has management appointed quality responsibility and authority to appropriate personnel?
3. Does the lab have a documented Quality System?
4. Does the management regularly review the Quality System at scheduled intervals?
5. Does the lab have a quality manual approved by management?
6. Are quality reports issued to management and used as a basis for continual improvement?
7. What accreditations does the laboratory maintain? Please list and attach copies.
8. Is there an SOP for sample submittal and receiving?
9. Is each sample assigned a unique laboratory identification number? How is it assigned?
10. Are samples stored securely and labeled with proper identity?
11. Is there a log of stored samples? For how long are samples stored?
12. Are temperature and humidity of sample storage area recorded?
13. Is a Certificate of Analysis (CofA) issued for each test performed?
14. Is all data on CofA's traceable to raw data stored by the laboratory?
15. How are CofA's for each customer stored? For how long?
16. Are clients notified of any method deviations taken during analysis? Is there a system for obtaining customer agreement to these changes?
17. Are there procedures to control, revise, and change documents?
18. Are all appropriate documents controlled and identified by revision level or date?
19. Do authorized personnel approve controlled documents prior to issue?
20. Are there SOP's available for handling reference standards and working standards?
21. Are CofAs and/or reference data for these standards available?

22. Are storage data and conditions available for these standards?
23. How often are standards re-analyzed or re-certified?
24. Do you have SOPs or guidelines on continual improvement?
25. Are SOPs and manuals available for handling all instruments?
26. Does the laboratory have a subcontractor list and approval system?
27. Does the laboratory conduct subcontractor audits? How often?
28. Are all reagents and chemicals sourced from approved suppliers?
29. Are reference standards certified (NIST or other)?
30. Are all reagents and chemicals marked with date of receipt, date opened, and expiration date? How are expiration dates assigned?
31. Does the laboratory have a documented calibration system?
32. Are there SOP's for calibration?
33. When calibration are performed by an outside contractor, does the laboratory require certifications and test data?
34. Are all calibrations traceable to NIST?
35. Are all analytical methods validated?
36. Are analytical method validation test data available?
37. Are all instruments currently certified to perform within the scope required for each analysis?
38. Are instruments calibrated? What is the calibration schedule?
39. Are weights used certified?
40. Is calibration data available for verification?
41. What are the procedures for re-testing a sample?
42. Are test results / chromatograms signed and dated by the analyst?
43. Is there a log for each instrument and piece of equipment? Is the log up to date?
44. Are laminar air flow stations validated for: velocity, filter integrity, linearity? How often?
45. Are records kept of temperature / pressure of each autoclave run?
46. Have you done heat distribution studies on the autoclave?
47. Are there SOP's for destruction of samples, media, and reagents?
48. Does the laboratory perform internal quality audits to verify that departmental personnel comply with established procedures?
49. Are follow-up audits performed in the case of any corrective action findings?
50. Are records of internal audits available?
51. Is there an SOP for observations that are outside of operating specifications?
52. Do you have an SOP for guidelines on Good Laboratory Practices (GLP)?
53. Are training records on each SOP available?
54. Is a training assessment of each analyst complete and certified?

IV. <u>Cannabis Qualifications</u>

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. What instruments are used for the analysis of cannabinoids?
2. How are cannabinoids reported?
3. Are cannabinoid acids and free form combined for a total potential free form cannabinoid calculations? How is this calculation performed?
4. What instruments are used for the analysis of terpenes?
5. How are terpenes reported?

6. How is moisture content of cannabis determined?
7. Are results reported on a dry weight basis? If so, how is the calculation performed?
8. Are any results reported other than direct analytes physically observed in the sample? (Such as total cannabinoids, total terpenes, total ocimene, etc) Please explain.

V. Pesticide Qualifications

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. What is the full list of pesticides analyzed by the lab?
2. Pesticide Instrumentation
   A. Are all pesticides able to be analyzed on a single instrument?
   B. If not, which analytes are assigned to which instrument?
3. How is the instrument(s) calibrated for pesticide analysis?
   A. Are pesticides calibrated individually or as a combined standard?
   B. Are pesticides calibrated in solvent standard or in spiked matrix?
   C. What are the concentrations used to generate a calibration curve for each pesticide?
   D. What are the correlation coefficients of the slopes generated from each analyte's curves?
4. What are the blank matrices use by the laboratory for pesticide analysis?
   A. From where is this matrix blank material sourced?
   B. Does this matrix blank material come with documentation certifying that is free of the pesticide residues being analyzed by the lab?
5. Extraction Procedures
   A. What method of extraction is used for extraction in each matrix analyzed by the laboratory for pesticides?
   B. Which equipment and reagents are used for this extraction?
   C. Has the laboratory performed experimentation to generate data on the spike recoveries of each pesticide in the corresponding matrix? If this data cannot be found in the quality manual or other requested laboratory documents, please attach it when submitting this form.
   D. Does the laboratory use the percentage recovery data to make any calculations used in final reported results? If so, please explain.
6. Quality Control
   A. How frequently does the laboratory perform QC checks on its pesticide analysis?
   B. What types of QC samples are performed for pesticide analysis?
   C. What are the mean recoveries, precisions and sample sizes of each type of QC sample from the previous calendar year?
   D. What are the mean recoveries, precisions and sample sizes of each type of QC sample from the current calendar year up to the present? (use client date of request or nearest practical date as 'the present')
7. Interfering Peaks
   A. What is the range in retention time seen from solvent standards?
   B. Is there a formal criteria for deviation in retention time during a client sample?
   C. If so, where is it cited, If not, which employees make this judgment call?

June 2023

Revision 12.0

COLORADO

Department of Public Health & Environment

General Audit Checklist for Marijuana Testing Facilities

Introduction

The Colorado Department of Public Health and Environment (CDPHE) **General Audit Checklist for Retail and Medical Marijuana Testing Facilities** (MTFs) serves as guidance and assistance to laboratories as they seek certification in a relevant category; additionally, the document reflects the rules and regulations applied by the auditors to determine if MTFs are adequately satisfying rules set forth by the Colorado Department of Revenue's (CDOR) Marijuana Enforcement Division (MED) to analyze retail marijuana and marijuana derived products. These guidelines are reflective of 1 CCR 212-3 and industry standards.

The objective of this document is to provide prospective MTFs with the same descriptions provided to the CDPHE auditors in determining precisely whether or not a MTF, or prospective MTF, adequately satisfies the requirements of MED.

CDPHE strongly recommends that MTFs utilize this document when seeking certification to assist in formulating and editing of documents and policies to satisfy requirements set forth by MED and prior to requesting site visits by CDPHE auditors. The MTF should have a large majority of the rules satisfied, prior to requesting site visits, in order for auditors to provide the MTF with the best service when seeking certification.

REQUIRED DOCUMENTATION
This section lists the documentation that the MTF must provide as evidence that it is in conformity with the requirement.

GUIDANCE
This section provides guidance specific to the required documentation. The purpose is to provide MTFs with the assistance they may need to develop the criteria that is required to obtain certification. Also, this section may describe the necessity for the documentation, procedure, policy, etc. that is being assessed. Types of materials may be described, e.g., SOPs, record retention policies, analytical data, etc.

Examples may be provided here.

For the purpose of clarity, the term "Test Batch" is used as the whole client sample package received by the laboratory.

The term "laboratory sample" is the sub-sample (smaller sample) the laboratory takes or extracts from the whole "Test Batch" (total sample) for the purpose of testing.

This section will assist the MTFs in determining what should be included in required documents, so they can satisfy the criteria set forth.

Evidence of Compliance:

- This section lists what the documents should contain, or
- This section lists what documents, in combination, satisfy the requirements

Yes ☐ No ☐ N/A ☐

REFERENCES: THIS IS WHERE THE REFERENCED RULE OR LINK TO AN INDUSTRY STANDARD WILL BE DISPLAYED

Comments: This is the comment section. This may be used by auditors to make notes regarding their findings while doing inspections. MTFs can use this section to make their own notes when applying the checklist to determine if they are ready to request an inspection by CDPHE.

Personnel:

MTFs provide complex laboratory services which require personnel to possess the qualifications necessary to ensure their professional competence. Corporate organization, as part of this section, ensures duties carried out by personnel are clearly defined and changes of personnel in key positions do not affect continuity of operations/certification. This section provides guidance for the baseline requirements for MTF personnel.

COLORADO
Department of Public Health & Environment

GENPER100
Does the laboratory employ a Laboratory Director with sufficient education and experience in order to obtain and maintain certification?

GENPER100

1. The Laboratory Director must be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
2. The Laboratory Director must hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; or
3. The Laboratory Director must hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
4. The Laboratory Director must hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.

Evidence of Compliance:

- Degrees of the Arts must be accompanied by transcripts.
- Provide a curriculum vitae (CV) demonstrating the required duration of experience in a regulated laboratory environment in which the testing methods were recognized by an accrediting body.
  *Research, clinical studies, and method development do not always qualify as regulated experience.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(11)

Comments: _____

GENPER200
Does the laboratory maintain complete and current documentation of education, training, and experience for the Laboratory Director and all analysts?

Yes ☐ No ☐ N/A ☐

GENPER200
The laboratory must provide documentation that demonstrates that the Laboratory Director and all analysts are competent to perform analysis. E.g., curriculum vitae (CV), resumes, training records, competency assessments, professional certifications, collegiate degrees or diplomas.

Competency and effectiveness of employee training shall be adequately assessed in an appropriate manner determined by the Licensee that is described in the standard operating procedures.

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(16); 3-9075(B)(16)(c)

Comments: _____

GENPER300
Has the Laboratory Director specified, in a comprehensive job description, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing?

Yes ☐ No ☐ N/A ☐

GENPER300
Documentation must identify which analyses and procedures each individual is authorized to perform, whether supervision is required for Test Batch processing, test performance, results reporting, and the review required prior to reporting results.

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(18)

Comments: _____

GENPER400
Does the Laboratory Director serve as the Supervisory Analyst?

Yes ☐ No ☐ N/A ☐

GENPER400
The Laboratory Director may also serve as a Supervisory Analyst or testing analyst, or both, for a MTF. A Supervisory Analyst can hold as much or as little responsibility as the Laboratory Director delegates, but the Supervisory Analyst must have the education/experience to make operational decisions (approve reports, method development, day-to-day scientific/operational decision making above the credentials of a testing analyst). The Supervisory Analyst is responsible for all duties delegated (in writing) by the Laboratory Director.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A)(1)

Comments: _____

GENPER500
If the Laboratory Director does not serve as the Supervisory Analyst, has delegation of these duties been made in writing and a record of delegation maintained?

Yes ☐ No ☐ N/A ☐

GENPER500
Delegation is the assignment of responsibility or authority to another person to carry out specific activities. Despite the delegation of a responsibility, the Laboratory Director is ultimately responsible for ensuring that delegated duties are performed properly and that all regulatory compliance/certification requirements for a MTF are met and maintained.

Written delegations provide documentation of assigned responsibilities and establish expectations to which the Supervisory Analyst can be held accountable.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A)(B)

Comments: _____

GENPER600
Is the Supervisory Analyst qualified?

GENPER600

1. Supervisory Analysts must meet one of the qualifications for a Laboratory Director; or
2. Have, at a minimum, a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.

Evidence of Compliance:

- Degrees of the Arts must be accompanied by transcripts.
- Provide a CV demonstrating experience in a regulated laboratory environment, conducting analytical-scientific testing in which the testing methods were recognized by an accrediting body.

*Research, clinical studies, and method development do not always qualify as regulated experience.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A)(B)

Yes ☐ No ☐ N/A ☐

Comments:_____

GENPER700
Are the Testing Analysts qualified?

Yes ☐ No ☐ N/A ☐

GENPER700
Educational Requirements. An individual designated as a Testing Analyst must meet one of the qualifications for a Laboratory Director or Supervisory Analyst or:
a. Have at least a bachelor's degree in one of the natural sciences and one year of full-time experience in laboratory testing;
b. Have a least a bachelor's degree in one of the natural sciences;
c. Have earned an associated degree in a laboratory science from an accredited institution; or
d. Have education and training equivalent to that specified in subparagraph (F)(1) of this Rule that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include:

i. 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and twelve semester hours of chemistry, biology, or cannabis laboratory sciences in any combination; and
ii. Have a laboratory training that includes at least three months documented laboratory training each testing category in which the individual performs testing; or

e. Have at least five years of full time experience in laboratory testing and have laboratory training that includes at least three months documented laboratory training in each testing category in which the individual performs testing.

REFERENCES: DOR 1 CCR 212-3 5/6-420(F)

Comments: _____

GENPER800
Are there a sufficient number of qualified laboratory personnel to ensure accurate performance of tests and reporting of test results?

Yes ☐ No ☐ N/A ☐

GENPER800
The laboratory must be adequately staffed to perform daily workloads and precise reporting, including providing appropriate consultation and adequate supervision of staff.

Evidence of Compliance:

- Is the laboratory meeting their published turn-around times?
- Is the laboratory reporting noncompliant Test Batches in METRC within 72 hours of obtaining final results?

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(20)

Comments: _____

GENPER900
Does the laboratory have a policy or procedure to provide a written notice to the Colorado Department of Public Health and Environment and the Marijuana Enforcement Division(MED) within seven days of the Laboratory Director's departure?

Yes ☐ No ☐ N/A ☐

GENPER900
In the event that the Laboratory Director leaves employment at a Marijuana Testing Facility, the Marijuana Testing Facility shall:

1. Provide written notice to the Colorado Department of Public Health and Environment and the Marijuana Enforcement Division within seven days of the Laboratory Director's departure; and
2. Designate an interim Laboratory Director within seven days of the Laboratory Director's departure. At a minimum, the interim Laboratory Director must meet the qualifications of a supervisory analyst.
3. The Marijuana Testing Facility must hire a permanent Laboratory Director within 60 days from the date of the previous Laboratory Director's departure, unless the Marijuana Testing Facility receives a written waiver from the Division Director.
4. A Marijuana Testing Facility may submit a waiver request to the MED Director to receive an additional 60 days to hire a permanent laboratory director provided that the Marijuana Testing Facility submits a detailed oversight plan along with the waiver request.

REFERENCES: CLINICAL LABORATORY IMPROVENT AMENDMENTS (CLIA) §493.51; DOR 1 CCR 212-3 5/6-420(D)(1)(2)(3)(4)

Comments: _____

GENPER1000
Does the Laboratory Director ensure that the overall analytical operation and quality of the results reported by the Marijuana Testing Facility are in compliance with the standards set forth in **Marijuana Rules 1 CCR 212-3?**

Yes ☐ No ☐ N/A ☐

GENPER1000
The Laboratory Director is responsible for the overall analytical operation and quality of the results reported by the Marijuana Testing Facility, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently and for assuring compliance with the standards set forth in **Marijuana Rules 1 CCR 212-3**.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A)

Comments: _____

Standard Operating Procedure:

SOPs provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently

GENSOP100
Has a written Standard Operating Procedure (SOP) Manual been established?

Yes ☐ No ☐ N/A ☐

GENSOP100
SOPs are uniformly written procedures with detailed instructions to perform routine operations, processes, and practices followed within an organization. SOPs help define the group's (e.g., unit, division, department, institution, etc.) standard practices and daily processes conducted to assure execution of tasks (pre-analytic, analytic, and post-analytic) in accordance with institutional and state guidance.

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(2);5/6-425(A)(1-24); http://hub.ucsf.edu/sops (paraphrased)

Comments: _____

GENSOP200
Has the SOP Manual, to include all approved methods, been signed and dated by the current Laboratory Director annually? (Not to exceed 12 months)

Yes ☐ No ☐ N/A ☐

GENSOP200
SOPs must be approved, signed and dated by the Laboratory Director prior to initial use, upon revision, and at least annually. Regular review of the laboratory procedures helps ensure in the in-use protocols are accurate and consistent with current practices. If any modifications are made to the procedures, the Laboratory Director must approve, sign and date the revision prior to use.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(4)(a)

Comments: _____

GENSOP300
Is the SOP Manual readily available to all analysts?

Yes ☐ No ☐ N/A ☐

GENSOP300
Accessibility (to the SOP Manual) can be either through paper-based or electronic formatting. Only the most recent and current SOPs should be available and some form of document control should be in place.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(4);5/6-420(C)(17)

Comments: _____

GENSOP400
Does the SOP Manual include criteria for Test Batch receiving?

Yes ☐ No ☐ N/A ☐

GENSOP400
Test Batch receiving criteria should include requirements/instructions for reviewing and documenting the receipt of Test Batches from the customer.

Marijuana facilities which double as certified hemp testing facilities, see HTF General Checklist for batch receiving requirements.

Evidence of Compliance:

- # of Test Batches received
- Type of Test Batch received (medical, retail, hemp)
- Signatures verifying who accepted and reviewed the manifest/requisition
- Verification of Test Batch weights and condition
- Instructions on how to receive Test Batches in METRC
- Verification that person submitting Hemp Test Batches is registered with the Commissioner of the Colorado Department of Agriculture

REFERENECES: DOR 1 CCR 212-3 5/6-405(E)(2)

Comments: _____

GENSOP500
Does the SOP Manual include criteria for Test Batch accessioning?

GENSOP500
The SOP criteria regarding Test Batch accessioning should explain how the laboratory tracks Test Batches from receipt, to analysis, to reporting, to storage. The criteria should also include a description of how accession numbers are created, internal labeling procedures, procedures for reviewing for clerical errors, and data-entry review.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(2)

Comments: _____

GENSOP600
Does the SOP Manual include criteria for Test Batch storage?

GENSOP600
The SOP criteria for Test Batch storage should include the laboratory's requirements for storing Test Batches upon receipt, throughout testing (unused Test Batches and extracts), and long term storage.
Parameters to consider:

- Temperature
- Recording dates of Test Batch storage and removal from storage
- Comments (e.g., reason for obtaining a Test Batch)
- Initials of the recorder

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(3)

Comments: _____

GENSOP700
Does the SOP Manual include criteria for identifying and rejecting unacceptable Test Batches?

Yes ☐ No ☐ N/A ☐

GENSOP700
Identification and rejection of Test Batches should be thoroughly explained to include (if applicable):

- Identification of who can reject Test Batches (e.g., Supervisor approval)
- Rejection based on administrative errors (e.g., Manifest information is incorrect, RFID on Test Batch does not match manifest, COC information incomplete, etc.)
- A Regulated Marijuana Testing Facility shall not accept a Test Batch that is smaller than its standard minimum amount.
- A Regulated Marijuana Testing Facility shall not accept a Test Batch if the Regulated Marijuana Testing Facility has reason to believe it was not collected in accordance with Test Batch collection requirements in Rule 4-110.
- Rejection based on observations (e.g., edible drink leaked from container, integrity seal not intact, edible not in proper package, obvious contamination, etc.)
- Procedure for handling rejected Test Batches.
    - Regulated marijuana plant material must be submitted to the laboratory in transparent packaging and the package content must not exceed 80% of the volume of the container.
    - Regulated marijuana products and delivery dose devices must be submitted to the laboratory in the packaging in which the item will be sold.

REFERENCES: DOR 1 CCR 212-3 3-1025(A-C); 5/6-425(A)(4); 4-115 (C)(1)(2)

Comments: _____

GENSOP800
Does the SOP Manual include criteria for Test Batch/laboratory sample preparation, including but not limited to, sub-sampling for testing, homogenization, and aliquoting laboratory samples to avoid contamination and carry-over?

Yes ☐ No ☐ N/A ☐

GENSOP800
A standard operating procedure manual must include, but need not be limited to, procedures for:

- Test Batch preparation, including but not limited to, sub-sampling for testing, homogenization, and aliquoting laboratory samples to avoid contamination and carry-over;

Comments: _____

GENSOP900
If adulteration for Sample Increment or Test Batch is suspected, does the SOP Manual include guidance to notify the Division and quarantine the Sample Increment or Test Batch for a minimum of 48 hours from the time of notification to the MED before proceeding with any testing? (**Effective July 1, 2023**)

Yes ☐ No ☐ N/A ☐

GENSOP900
Effective July 1, 2023, if a Regulated Marijuana Testing Facility suspects or has reason to suspect a Sample Increment or Test Batch has been adulterated, the Regulated Marijuana Testing Facility must:

a. Notify the MED; and
b. Quarantine the Sample Increment or Test Batch for a minimum of 48 hours from the time of notification to the Division before proceeding with any testing.

REFERENCES: DOR 1 CCR 212-3 4-115 (C)(3)

Comments: _____

GENSOP1000
Does the SOP Manual include criteria for the photo documentation of Test Batches?

Yes ☐ No ☐ N/A ☐

GENSOP1000
The laboratory must take a digital photograph of each Test Batch received for testing to document the condition of the Test Batch.

REFERENCES: DOR 1 CCR 212-3 3-1025(A-C); 4-115(B)(2)

Comments: _____

GENSOP1100
Does the SOP Manual include criteria for recording and reporting discrepancies?

Yes ☐ No ☐ N/A ☐

GENSOP1100
The laboratory must have processes to record and report discrepancies throughout the pre-analytic, analytic, and post-analytic phases of operation.
Some examples of discrepancies:

- Weight discrepancy between METRC and weight upon receipt at laboratory.
- Debris found in Test Batch.
- Analytical laboratory sample vial broken during transfer to instrument.
- Administrative reporting errors.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(5)

Comments: _____

GENSOP1200
Does the SOP Manual include criteria for security of Test Batches, aliquots, extracts, and records?

Yes ☐ No ☐ N/A ☐

GENSOP1200
The SOP must describe the measures taken by the laboratory to ensure the security of Test Batches/aliquots/extracts upon intake, short-term storage, testing, and long-term storage. Additionally, the security of both paper and digital records that are in use and under long-term storage must be addressed.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(6)

Comments: _____

GENSOP1300
Does the SOP Manual include criteria that ensures Test Batches and Industrial Hemp Products are tested as received, are not manipulated, and tested in a manner that ensures results are representative of Test Batches as received?

Yes ☐ No ☐ N/A ☐

GENSOP1300
All Test Batches and Industrial Hemp Product must be tested as received, must not be manipulated, and tested in a manner that ensures results are representative of Test Batch as received.

REFERENCES: DOR 1 CCR 212-3 5/6-430 (K)

Comments: _____

GENSOP1400
Does the SOP Manual include criteria for Test Batch retention to assure stability for 14 days for all products? (Except for Pesticide Test Batches/laboratory samples, which must be stored for 90 days.)

Yes ☐ No ☐ N/A ☐

GENSOP1400
All Test Batches remaining after testing must be securely stored by the MTF for 14 days except for Pesticide Test Batches/laboratory samples (90 days).

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(9)

Comments: _____

GENSOP1500
Does the SOP Manual include criteria for Test Batch/laboratory sample disposal?

GENSOP1500
Marijuana and marijuana product waste must be made unusable and unrecognizable prior to leaving the licensed premises. The laboratory must grind or incorporate the marijuana waste with non-consumable, solid wastes such that the resulting mixture is at least 50% non-marijuana waste or the laboratory may utilize on-site composting, anaerobic digestion, pyrolyze into biochar, or biomass gasification. Rendered waste must be disposed of at a disposal or compost facility that has a Certificate of Designation from CDPHE or composted on-site at a facility owned by the generator of the waste and operated in compliance with the Regulations Pertaining to Solid Waste Sites and Facilities (6 CCR 1007-2, Part 1).

A Regulated Marijuana Business may transfer Vaporizer Delivery Device waste prior to being made unusable and unrecognizable for purposes of grinding or compacting the Vaporizer Delivery Device waste at the Licensed Premises of another Regulated Marijuana Business.

Compounds that can be used for the waste mixture:

- Paper waste
- Plastic waste
- Cardboard waste
- Food waste
- Grease or other compostable oil waste
- Bokashi or other compost activators
- Other wastes, ***approved by the Division*** (written approval from MED must be available during CDPHE audit) that will render the marijuana waste unusable and unrecognizable
- Soil

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 3-230(D-E); 5/6-425(A)(10); 3-230 (D)(1)

Comments: _____

GENSOP1600
Does the SOP Manual or Quality Manual include procedures and/or protocols for general laboratory upkeep and cleaning?

Yes ☐ No ☐ N/A ☐

GENSOP1600
The laboratory must officially outline protocols and procedures regarding general housekeeping. Laboratory housekeeping is important to maintain overall laboratory quality and poor housekeeping may directly affect the quality of analytical results. Specifically, mycotoxins may be lost or carried over due to the use of improperly washed glassware/laboratory equipment; the proper cleaning of laboratory glassware and other relevant laboratory items is extremely important and must be outlined in the appropriate SOPs.

REFERENCES: Latimer, George. *Official Methods of Analysis of AOAC INTERNATIONAL*, 20th Edition (AOAC International, Gaithersburg, 2016)

Comments: _____

GENSOP1700
Does the SOP Manual include criteria, for the validation of new or revised methods, where applicable, prior to testing Test Batches?

Yes ☐ No ☐ N/A ☐

GENSOP1700
All new and revised analytical methods must be validated and SOP criteria must, at minimum, include the following parameters: accuracy, precision, analytical sensitivity, analytical specificity (interferences), limit of detection (LOD), limit of quantification (LOQ), and verification of the reportable range.

MTFs must provide revised methods to CDPHE where there are major revisions prior to implementation. Major method changes include, but are not limited to: modifications to Test Batch/laboratory sample preparation, changes in column type, changes in enrichment media, changes in solvent(s) used, etc.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(7)

Comments: _____

GENSOP1800
Does the SOP Manual include criteria establishing a documented system for reviewing the results of testing calibrators, controls, standards, and test results; as well as reviewing for clerical errors, analytical errors, and any unusual analytical results?

Yes ☐ No ☐ N/A ☐

GENSOP1800
The documented system/procedure for review of routine/daily testing must include; but is not limited to, review of:

- Calibrators
- Controls
- Standards
- Test results (ensure that test results are reported in the proper units for Test Batches, and all of the aforementioned checks and balances were, in fact, reviewed).
- Administrative errors (errors in data entry, results, client information, etc.)
- Analytical errors (calculations, dilution factors, etc.)
- Any unusual analytical results (peak shaving, calibration point removal, etc.)
- Contacting requesting entity for clarification, additional analyses, or when testing does not meet established levels of quality.

Review must be documented to reflect that each analytical result reported has been evaluated for the aforementioned examples, to ensure the accuracy of the final report. This process must include at least two levels of review. Evidence of Compliance:

- Multiple levels of sign-offs on batch sheets
- Daily reporting review sign-off sheets
- QC checklists
- Etc.

REFERENCES: DOR 1 CCR 212-35/6-425(A)(16)(20)(23)(24)

Comments: _____

GENSOP1900
Does the SOP manual include policies and procedures for testing Industrial Hemp?

Yes ☐ No ☐ N/A ☐

GENSOP1900
The laboratory's SOP manual must specify a logistical difference between Hemp and other cannabis products (Recreational, Medical and Industrial Hemp).

REFERENCES: DOR 1 CCR 212-3 6-405(E - F)

Comments: _____

GENSOP2000
Does the laboratory adhere to the approved standard operating procedures as written?

Yes ☐ No ☐ N/A ☐

GENSOP2000
The laboratory must follow the current, approved SOPs and perform the tests as required by the procedure(s) for accurate and reliable results.

REFERENCES: DOR 1 CCR 212-3 6-420(C)(2);5-440(B)(18)

Comments: _____

GENSOP2100
Does the laboratory document all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the Standard Operating Procedure?

Yes ☐ No ☐ N/A ☐

GENSOP2100
The laboratory SOP must include procedures for:

- Issuing and documenting corrective actions when acceptability criteria are not met.
  Evidence of Compliance:
  - Corrective action forms
  - Preventative action forms
  - Documentation of follow-up actions

REFERENCES: DOR 1 CCR 212-3 5-440(B)(1)(16)

Comments: _____

GENSOP2200
Does the SOP Manual include procedures for contacting the requesting entity about existing Nonconformances?

Yes ☐ No ☐ N/A ☐

GENSOP2200
The laboratory SOP manual must include a procedure for contacting the requesting entity about existing nonconformances.

REFERENCES: DOR 1 CCR 212-3 5/6-425 (A)(23)

Comments: _____

GENSOP2300
Does the SOP Manual include policies and procedures for retesting or additional analyses of Test Batches, including but not be limited to, when it is appropriate to retest or perform an additional analysis of the Test Batch, when it is appropriate for the requesting entity to request retesting to follow when Test Batches are requested for referral for testing by another certified laboratory?

Yes ☐ No ☐ N/A ☐

GENSOP2300
The laboratory SOP must include procedures for;

- Retesting or additional analyses of Test Batches, including but not be limited to, when it is appropriate to retest or perform an additional analysis of the Test Batch, when it is appropriate for the requesting entity to request retesting (e.g., after failing Pesticide testing or elemental impurity testing on Regulated Marijuana flower, trim, shake, or wet whole plant as permitted by Rule 4-135(D) and 4-135(D.1)).

REFERENCES: DOR 1 CCR 212-3 5/6-425 (A)(24)

Comments: _____

GENSOP2400
Does the SOP Manual include policies and procedures to follow when Test Batches are requested for referral for testing by another certified laboratory?

Yes ☐ No ☐ N/A ☐

GENSOP2400
A laboratory must have policies and procedures in place that follow METRC requirements for transfer of Test Batches. These policies and procedures may also help as part of a contingency plan for continuity of operations for the MTF.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(21)

Comments: _____

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GENSOP2500
Does the SOP Manual include a procedure for the reporting of any potentially hazardous contaminant (not required for testing) found during routine testing?

Yes ☐ No ☐ N/A ☐

GENSOP2500
The laboratory must have a policy or procedure in place that addresses the handling and reporting of any potentially hazardous contaminants that may be encountered during routine testing.

The Regulated Marijuana Testing Facility must notify the Regulated Marijuana Business and the Division and initiate corrective actions with all parties.

Division Notification: A Regulated Marijuana Testing Facility must notify the MED by timely input in the Inventory Tracking System if a Test Batch is found to contain levels of a contaminant not listed within Rule that could be injurious to human health if consumed.

The laboratory must report a Test Batch as having failed contaminant testing if testing identifies:

- Levels of any chemical that could be toxic if consumed
- Levels of any microbial that could be toxic if consumed
- Levels of any mold, mildew, or filth that could be toxic if consumed
- Levels of other contaminants that could be injurious to human health if consumed

REFERENCES: DOR 1 CCR 212-3 4-115(D)(6)(7)

Comments: _____

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Environment, Health and Safety:

Employee health and safety is of tantamount importance. Laboratory spaces must be kept secure, safe and well maintained. Laboratories' must establish safety protocols, evacuation protocols, safe waste protocols, etc., and ensure staff is trained in these procedures in order to ensure staff remains safe in the face of adverse events.

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GENEHS100
Does the laboratory establish a protocol which provides information for staff in the event of an emergency?

Yes ☐ No ☐ N/A ☐

GENEHS100
The laboratory must protect employees from emergency situations by providing information regarding the handling of emergency events. Such events may include inclement weather, active shooter, fire, etc. The laboratory must post evacuation maps, provide employees with some form of emergency notification, make available an emergency action plan or equivalent, and provide spill kits as required. The laboratory should provide any additional safety items necessary for each uniquely identified situation as required.

Evacuation maps shall contain:

- Primary and secondary exit routes
- The location of emergency equipment (AED, Fire extinguishers, first aid kits, eye wash/safety showers, etc.)
- Fire alarm pull stations
- Primary/secondary assembly areas

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(4); OSHA 29 CFR 1910.38

Comments: _____

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GENEHS200
Does the laboratory provide safety equipment?

Yes ☐ No ☐ N/A ☐

GENEHS200
The laboratory shall provide general safety equipment for employees. Safety equipment must include, but is not limited to: operational fire extinguishers, eye wash and safety showers clean and clear electrical panels and emergency exits.

Inspections:

- Fire Extinguishers
  - Monthly visual
  - Annual Maintenance check
- Safety Shower/Eye wash
  - Eye wash weekly activation
  - Safety shower routinely checked

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(4); OSHA 29 CFR 1910.157, 29 CFR 1910.1450, ANSI Z358.1

Comments: _____

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GENEHS300
Does the laboratory properly manage and store generated hazardous waste?

GENEHS300
The laboratory shall provide adequate and proper hazardous waste containers, such as waste drums or containers for liquid wastes, biological waste bags and waste container and boxes for generated sharps. Each liquid container must be labeled and must sit in a secondary containment unit. The name(s) and number(s) of the waste management organization(s) which removes/manages the waste should be available to staff.

Labels must include:

- "Hazardous waste"
- General contents
- Hazard communications/NFPA code label
- Accumulation start date

Yes ☐ No ☐ N/A ☐

REFERENCES: 1CCR 212-3, 3-230 (C); 40 CFR 262, 6 CCR 1007-3;

Comments: _____

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GENEHS400
Does the Laboratory Director ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards?

Yes ☐ No ☐ N/A ☐

GENEHS400

- The laboratory's QAP must include chemical and biological safety plans and training that are appropriate for the testing performed. (These may be separate documents from the laboratory's Quality Assurance Manual (QAM)).
- The laboratory must provide staff with personal protective equipment (PPE) appropriate for the testing performed.
- The laboratory must ensure the physical location and environmental conditions are appropriate for the testing performed.
    - For example:
        - If working with toxic chemicals or bacteria the laboratory must have a fume hood and/or appropriate class of biological safety cabinet (BSC)
            - ❖ Hoods must be certified annually
        - MSDS' or SDS' should be organized and readily available to all laboratory staff
        - Appropriate signage in hazardous areas (chemical/biohazard)
        - Spill kits must be available
        - The laboratory must have an ABC fire extinguisher
        - The laboratory must have a hand-washing station
        - The laboratory must have an eye-washing station
        - The laboratory must have a designated space for eating and drinking, segregated from the laboratory testing area
- Laboratories should review their operations in terms of the applicable industry, federal, or local regulations/guidance and consult with appropriate regulatory agencies for assistance or guidance.

The laboratory should provide a neat, clean and safe laboratory for employees. For example, gas cylinders secured, functional fume hoods, flammable cabinets and clean and appropriate PPE. Also, the laboratory is required to have a Chemical Hygiene Plan and an emergency contact list available. Rooms with limited access should have an up to date roster.

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(4); OSHA 29 CFR 1910.94, 29 CFR 1910.1450, 29 CFR 1926.152, 29 CFR 1926.350, NFPA 1

Comments: _____

Analytical Processes:

The analytical process can be described as consisting of four principle stages of operation:

1. Sampling
2. Isolation/separation of the desired constituent in a measureable state
3. Measurement of the desired constituent
4. Calculation and interpretation of the data

P. J. Elving, *Anal. Chem.*, **1950**, *22* (8), pp 962–965 **DOI:** 10.1021/ac60044a002 Publication Date: August 1950

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GENINS100
Does the laboratory perform and document instrument preventative maintenance and repair as required by the manufacturer?

Yes ☐ No ☐ N/A ☐

GENINS100
Documentation of instrument maintenance is important to help with troubleshooting and ensure that all manipulations to instruments are performed in accordance with the manufacturer's recommendations. Logs should be maintained to document all maintenance events (daily, weekly, monthly, quarterly, annually, etc.) and include, at a minimum: dates, identity of person conducting the work, description of action(s), and secondary review.

Instrument maintenance should only be performed by trained/qualified personnel, which should be reflected within their competency assessments if the analyst is approved to perform maintenance.

REFERENCES: DOR 1 CCR 212-3 5/6-430(A)(2);(B)(1);(C)(1);(E)(1);(F)(1)

Comments: _____

GENINS200
Does the laboratory evaluate and document the performance of instruments after routine and preventative maintenance and prior to analyzing laboratory samples?

Yes ☐ No ☐ N/A ☐

GENINS200
After instruments have adjustments made or have maintenance performed, the instrument must be evaluated. This can be accomplished by analyzing controls/calibrators and blanks by which the results must meet the acceptability criteria set forth by the laboratory. All preventative maintenance must be documented in an instrument maintenance log and approved by a supervisory analyst/designee, prior to analyzing laboratory samples.

REFERENCES: DOR 1 CCR 212-3 5/6-430(B)(14)5/6-440(A)(1)

Comments: _____

GENINS300
Does the laboratory perform and document instrument troubleshooting and corrective actions when performance does not meet established levels of quality?

Yes ☐ No ☐ N/A ☐

GENINS300
The levels of quality are established by the laboratory's acceptability criteria and SOPs. When an instrument malfunctions or when quality control doesn't meet established acceptability criteria it needs to be documented with follow-up actions. Corrective action documentation should include, at a minimum:

- The reason for issuing corrective action
- The individual assigned responsibility for action resolution
- The date the problem occurred
- The date by which the problem is to be resolved
- Root cause analysis
- The magnitude of the problem (was customer data affected?)
- Signature and date of completion
- Follow-up actions
- Results of follow-up actions
- Monitoring (review) of results to ensure the effectiveness of the action taken.

REFERENCES: DOR 1 CCR 212-3 5/6-440(A)(1);(B)(16)

Comments: _____

GENINS400
Does the laboratory ensure that records are maintained and readily available to the staff operating the equipment?

Yes ☐ No ☐ N/A ☐

GENINS400
Instrument and equipment records (maintenance logs, calibration certificates, manufacturer preventative maintenance reports, etc.) must be maintained and available to the staff either electronically or physically. For example: Keeping these records in a locked filing cabinet, not readily accessible to staff, is not acceptable.

REFERENCES: DOR 1 CCR 212-3 5/6-430(A)(3)

Comments: _____

Proficiency Testing:

Laboratory Standardization is achieved when test results with the same high levels of accuracy and precision can be reproduced across measurement systems, laboratories, and over time. Proficiency testing ensures the production of credible and comparable data across laboratories. (http://www.cdc.gov/labstandards/)

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GENPRO100
Has the laboratory successfully participated in a Proficiency Testing (PT) program in the category for which it seeks initial certification? (Within the preceding 12 months)

Yes ☐ No ☐ N/A ☐

GENPRO100
The levels of quality are established by the laboratory's acceptability criteria and SOPs. To obtain initial certification, MTFs must successfully participate and pass proficiency testing by positively identifying at least 80% of the target analytes that the MTF reports. Incorrect identification of more than 20% of the analytes tested will be considered unsatisfactory. Any false positive results reported will be considered an unsatisfactory score for the proficiency testing event.

Recommendation for suspension of certification will be made for the relevant testing category if two consecutive unsatisfactory Proficiency Testing events occur, or if two out of three consecutive unsatisfactory Proficiency Testing events occur. Certification may be reinstated after successful participation in the next Proficiency Testing event. Failure to achieve a satisfactory score in the next test event will result in recommendation for the revocation of the certification and will require two successful consecutive Proficiency Testing events before the Testing Facility may be eligible to reapply for certification.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(6);5/6-420(C)(8);5/6-435(A)(B)(C); MED 200909 Proficiency Testing Compliance Tip

Comments:_____

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GENPRO200
Is the laboratory participating in a Proficiency Testing (PT) program for each approved category, biannually, in which it seeks continuing certification?

Yes ☐ No ☐ N/A ☐

GENPRO200
To maintain certification MTFs must successfully participate and pass proficiency test samples twice per year for the category for which they are seeking continued certification. These blinded samples help ensure that the clients are receiving accurate quality results from a certified laboratory, regardless of methodology used.

Laboratories must participate in proficiency testing programs which offer varying matrices. Laboratories must rotate matrices to adequately cover matrices routinely tested by the laboratory.

REFERENCES: DOR 1 CCR 212-3 5/6-435(B)(H)

Comments:_____

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GENPRO300
Does the Laboratory Director and all testing analysts that participated in a PT event sign corresponding attestation statements?

GENPRO300
All analyst(s) testing/handling the proficiency samples and the Laboratory Director must attest to the routine integration of the samples into the work load using the laboratory's standard method. This is usually a separate form that all involved sign, confirming their knowledge of PT sample handling and holding accountability requirements.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-435(B)(H)

Comments: _____

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GENPRO400
Does the laboratory analyze PT samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment as used for product testing?

Yes ☐ No ☐ N/A ☐

GENPRO400
PT samples should be treated as routine testing; meaning they should go through the same end-to-end process that all client Test Batches endure. This will help evaluate the laboratory's entire process and could possibly determine problems internally. If any special handling is necessary the laboratory should document any necessary reconstitution, longer mixing times, unit conversion of results, etc. PT samples are not allowed to be reanalyzed to confirm results, analyzed in duplicate, or analyzed with additional QC unless that is normal practice for all client Test Batches.

Evidence of Compliance:
- Evidence of accessioning
- Evidence of photographic documentation (if applicable)
- Evidence of preparation
- Analytical data
- Report
- Etc.

REFERENCES: DOR 1 CCR 212-3 5/6-435(D)

Comments: _____

GENPRO500
Does the Laboratory Director review and evaluate performance on all PT events?

Yes ☐ No ☐ N/A ☐

GENPRO500
The laboratory must document that the Laboratory Director reviews and evaluates all PT results, whether acceptable or unacceptable. It is recommended that laboratories also share the results within their organization (at least with the analysts involved) and also document their review.

REFERENCES: DOR 1 CCR 212-3 5/6-435(F)

Comments: _____

GENPRO600
Does the laboratory retain all PT documentation? (For a minimum of five years)

Yes ☐ No ☐ N/A ☐

GENPRO600
Evidence of Compliance (including but not limited to):

- Accessioning records
- Photographs (if applicable)
- Preparation records
- Analytical data
- Reports
- PT Results
- Etc.

REFERENCES: DOR 1 CCR 212-3 5/6-450(B)(6)

Comments: _____

GENPRO700
Does the laboratory take and document remedial actions when a score of less than 100% is achieved during a PT event to include a review of samples tested and results reported since the last successful PT challenge?

Yes ☐ No ☐ N/A ☐

GENPRO700
The laboratory's corrective action/non-conformance process should be initiated when a score of less than 100% is earned during a PT event.

This could include, but is not limited to, an internal investigation covering:

- Examination of submitted results and received reports for discrepancies or clerical errors.
- Method history review (i.e., maintenance, reagents, etc.)
- History of previous survey problems.
- Proficiency sample material problem(s) investigation (i.e., handling, reconstitution, storage, analysis sequence, participants/referees discrepancy).

REFERENCES: DOR 1 CCR 212-3 5/6-435(G)

Comments: _____

Competency Assessments:

Laboratory Standardization is achieved when test results with the same high levels of accuracy and Competency assessments evaluate an employee's ability to adequately perform job duties. The assessments can be utilized to determine if an analyst is fully trained and allowed to perform duties independently or if additional training, remedial training, or removal from the analysis is required.

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GENCOM100
Does the laboratory ensure that prior to testing any Test Batches, all testing analysts receive the appropriate training for the type and complexity of tests performed and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results?

Yes ☐ No ☐ N/A ☐

GENCOM100
Appropriate training for the type and complexity of testing performed is a discretionary term that must be taken with proper consideration and may possibly include performance of a risk assessment to determine the training necessary to ensure that all testing operations are reliably executed to provide and report accurate results.
For example: Analytical balance operation or autoclave operation may seem like a remedial task; however, the downstream effects of improper use could lead to inaccurate test results or serious injury.

Prior to independently analyzing Test Batches, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(3)(b); 5/6-420(C)(15)

Comments: _____

GENCOM200
Does the laboratory have written policies and procedures for monitoring individuals who conduct pre-analytic, analytic, and post-analytic phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills?

Yes ☐ No ☐ N/A ☐

GENCOM200
MTFs must have a written and documented system to evaluate and document employee competency in performing authorized tests. The written policies and procedures must include the evaluations of employees performing accessioning and reporting.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(3)(b); 5/6-420(C)(16)

Comments: _____

GENCOM300
Are competency assessments performed and documented on all new Supervisory and Testing Analysts prior to reporting results?

Yes ☐ No ☐ N/A ☐

GENCOM300
Prior to independently analyzing Test Batches, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls).

Documentation of competency assessments should include, but is not limited to:

- Evidence of review of relevant policies, procedures, and literature
- Observation of all test processes and instrument functions
- Successful performance of testing
- Data review
- Reporting

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(3)(b); 5/6-430(I)(4)

Comments: _____

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GENCOM400
Are competency assessments performed and documented on all Supervisory and Testing Analysts annually for all approved methods being used or when modifications to existing methods are made prior to reporting results?

Yes ☐ No ☐ N/A ☐

GENCOM400
Supervisory and Testing Analysts must, at a minimum, annually (or upon method modification) demonstrate continued acceptable competency.

Documentation of competency assessments should include, but is not limited to:

- Evidence of review of relevant policies, procedures, and literature
- Observation of performance of all test processes and instrument functions
- Successful performance of testing
- Proper data review
- Correct reporting

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(3)(b); 5/6-430(I)(4)

Comments: _____

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Quality Assurance & Quality Control:

Laboratory Quality Assurance Programs (QAP) encompass a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. Test results produced by MTFs have a significant influence on public health and industry product acceptability. A good QA program *at least*:

- Establishes SOPs for each step of the laboratory testing process, ranging from specimen handling to instrument performance validation.
- Defines administrative requirements, such as mandatory recordkeeping, data evaluation, and internal audits to monitor adherence to SOPs.
- Specifies corrective actions, documentation, and the persons responsible for carrying out corrective actions when problems are identified

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GENQAP100
Has the laboratory established and continuously monitored and documented the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory's pre-analytic, analytic, and post-analytic systems when they occur?

Yes ☐ No ☐ N/A ☐

GENQAP100
The laboratory's QAP must have an established, documented method (policy/SOP) for the ongoing review of the QAP. A recommended method for continuously monitoring and documenting the ongoing review of the QAP would be internal audits. Internal audits can monitor adherence to SOPs and the QAP through document review.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(7); 5/6-420(A);(C)(9); 5/6-440(A)

Comments: _____

GENQAP200
Is the review of quality assurance documentation performed by the Laboratory Director or designated Supervisory Analyst on an ongoing basis to ensure the effectiveness of actions taken over time?

Yes ☐ No ☐ N/A ☐

GENQAP200
The laboratory's QAP must include the process by which and how the laboratory intends to review QA documentation. Corrective actions of nonconformance must be reviewed (at least annually) to ensure the effectiveness of the actions taken. Depending on the severity of the nonconformance (or actions taken), the length of time and/or intervals of time needed to review the effectiveness of actions taken is at the discretion of the Laboratory Director or designated Supervisory Analyst.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(A)

Comments: _____

GENQAP300
Does the Laboratory Director or designated Supervisory Analyst review the performance of validated methods used by the laboratory to include: calibration standards, controls, and the SOPs used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed?

Yes ☐ No ☐ N/A ☐

GENQAP300
The laboratory QAP must include the process by which and how the laboratory intends to review the performance of validated methods. The written policies/procedures must include what is to be reviewed, by whom, the frequency of review, and how this review will be documented. The Laboratory Director and/or designated Supervisory Analyst may perform this review through a combination of internal audits, corrective actions/non-conformance reviews, analytical/QC data review and approval, and SOP review and approval at least annually.

1 CCR 212-3 5/6-420(A); 5/6-440(A)(2)(3)

Comments: _____

GENQAP400
Does the laboratory ensure that the test methodologies selected have the capability of providing the quality of results required for the level of the testing the laboratory is certified to perform?

Yes ☐ No ☐ N/A ☐

GENQAP400
The laboratory must ensure that testing systems developed and used for each of the tests performed provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing. This entails ensuring that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and that laboratory personnel are performing the test methods as required for accurate and reliable results.
The laboratory must select methods or have assurances in place that at a minimum, under normal circumstances (proper equipment functionality, trained staff, etc.), should be capable of reasonably detecting problems with the method, a matrix, total effectiveness, or other variables that could affect the quality of results.

Comments: _____

GENQCM100
Has the laboratory established, continuously monitored, and documented the quality control measures taken by the laboratory to ensure the proper functioning of equipment, validity of SOPs, and accuracy of results reported?

Yes ☐ No ☐ N/A ☐

GENQCM100
The laboratory must provide evidence that quality control measures are monitored and documented, such as QC sheets for daily analysis, with at least primary and secondary review, or instrument maintenance logs with periodic secondary review.

Evidence of Compliance:

- Signatures/initials and dates on prep sheets, QC sheets, logs, etc.

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(9); 5/6-440(A)(B)

Comments: _____

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GENQCM200
Does the laboratory review and document the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter?

Yes ☐ No ☐ N/A ☐

GENQCM200
Evidence of Compliance:

- Annual service/calibration certificate documentation must be available.
  - This can be performed in-house or by an outside vendor.
- In-house service/calibration requires:
  - SOP for the process
  - Documented annual training of technicians
  - Competency in accurately performing the service/calibration

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(2)

Comments: _____

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GENQCM300
Does the laboratory document the cleaning, maintenance, calibration and verification of the analytical balances?

Yes ☐ No ☐ N/A ☐

GENQCM300
The laboratory should use an "Analytical Balance Maintenance Log" to document the cleaning, maintenance, and calibration of analytical balances; the log should be reviewed periodically by a secondary reviewer. Balances should be verified using weights bracketing the range of measurement as frequently as the balance is in use (i.e., daily, weekly, etc).

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(3)

Comments: _____

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GENQCM400
Does the laboratory annually verify the calibration of analytical balances using certified weights to include; three or more NIST traceable weights, bracketing the ranges of measurement used by the laboratory?

Yes ☐ No ☐ N/A ☐

GENQCM400
Evidence of Compliance:

- Annual service/calibration certificate documentation must be available.
  - This can be performed in-house or by an outside vendor.
  - In-house service/calibration requires:
    - SOP for process
    - Documented annual training of technicians
    - Competency in accurately performing the service/calibration
    - Annually calibrated NIST traceable weights

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(3)

Comments: _____

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GENQCM500
Does the laboratory annually verify and document the accuracy of thermometers using a NIST traceable reference thermometer?

Yes ☐ No ☐ N/A ☐

GENQCM500
Evidence of Compliance:

- Annual service/calibration certificate documentation must be available.
  - This can be performed in-house or by an outside vendor.
  - In-house service/calibration requires:
    - SOP for process
    - Documented annual training of technicians
    - Competency in accurately performing the service/calibration
    - Annually calibrated NIST traceable thermometer

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(4)

Comments: _____

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GENQCM600
Does the laboratory record temperatures on all equipment when in use where temperature control is specified in the SOPs Manual or required by reagents, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers?

Yes ☐ No ☐ N/A ☐

GENQCM600
Temperature charts/logs are required to ensure the laboratory is monitoring the temperature dependent instruments, reagents, and processes, per the requirements established by the manufacturer or method. This assists the laboratory with identifying possible non-conformances, prior to analysis.

- Temperature ranges (e.g., 2-8 ºC) should be stated on the temperature charts/logs to assist in identifying non-conformances.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(5)

Comments: _____

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GENQCM700
Does the laboratory ensure reagents are properly labeled?

Yes ☐ No ☐ N/A ☐

GENQCM700
Reagent bottles/containers must be labeled even if they are recorded in a "Reagent Preparation Log".
Evidence of Compliance: (must include but is not limited to)

- Received dates
- Receiver's initials
- Expiration dates
- Opened dates
- Initials of opener
- Storage conditions
- Lot number

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(6)

Comments: _____

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GENQCM800
Does the laboratory properly label and track in-house prepared solutions that identify: solution contents, the concentration, date of preparation, storage conditions, lot number (if applicable), expiration date, and the identity of the preparer?

Yes ☐ No ☐ N/A ☐

GENQCM800
Solution bottles/containers must be labeled even if they are recorded in a "Solution Preparation Log". Solutions will acquire the earliest expiration date of listed ingredients. If no expiration date is available, the lab will set an expiration date.
Evidence of Compliance: (must include but is not limited to)

- Preparation dates
- Preparer's initials
- Expiration dates
- Initials of opener
- Storage conditions
- Lot number (Generated by the laboratory if made in-house)

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(6)

Comments: _____

_____

_____

GENQCM900
Does the laboratory avoid mixing different lots of reagents in the same analytical run?

Yes ☐ No ☐ N/A ☐

GENQCM900
Using different lot numbers of reagents in the same analytical run increases the scientific variability introduced to troubleshooting if non-conformances are encountered. The laboratory should document lot numbers for all reagents, solutions, kits, etc. for each analytical run.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A); 5/6-440(B)(7)

Comments: _____

GENQCM1000
Does the laboratory document and ensure that reagents and solutions perform properly prior to analyzing Test Batches/laboratory samples?

Yes ☐ No ☐ N/A ☐

GENQCM1000
Reagents can be compromised during shipment or storage, and solutions can be incorrectly measured by simple technical errors, for example. To ensure that the quality of received reagents and verify that in-house prepared solutions meet established performance criteria, they must be tested. The manufacturer's Certificate of Analysis is not acceptable documentation of performance, as reagents can be compromised in the aforementioned situations.

It is permissible to conduct this testing as part of a live run, although this may result in the loss of a batch if established performance criteria are not met.

REFERENCES: DOR 1 CCR 212-3 5/6-420(A)

Comments: _____

Test Batch Tracking:

Test Batch tracking is an important component of Quality Control and is imperative to maintaining chain of custody. Test Batch tracking ensures proper Test Batch identification from acceptance to destruction and accuracy in reported test results.

GENSAM100
Has the laboratory established an adequate Test Batch tracking system?

Yes ☐ No ☐ N/A ☐

GENSAM100
Test Batch tracking within a laboratory must be capable of individually identifying every Test Batch/laboratory sample throughout pre-analytical, analytical, post-analytical activities. Retail Marijuana, Medical Marijuana and Industrial Hemp must be identified and separately traceable through the entire process.

REFERENCES: DOR 1 CCR 212-3 5/6-410 (G) 3-805 (B)(D)(2)(E)(1-4)(F)(1-3)(G)(1-2)(H)(I) 5/6-415 (C)(9) 5/6-425 (A)(1)(2)(3)(4)(5)(6) (21) 5/6-445 (1-11)

Comments: _____

_____

_____

GENSAM200
Does the laboratory issue instructions to customers for the minimum Test Batch and storage requirements for acceptance?

Yes ☐ No ☐ N/A ☐

GENSAM200
Test Batch instructions should include, but not be limited to:

- Minimum Test Batch requirements
- Storage conditions if applicable
- Container type (e.g., edibles must be in final packaging)
- Packaging and shipping instructions
    - Sealed, tamper-evident shipping container
- Reasons for rejection

REFERENCES: DOR 1 CCR 212-3 5/6-445(A)(1); 4-115(B)(1)(2)

Comments: _____

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GENSAM300
Does the laboratory document the condition of the external package and integrity seals utilized to prevent contamination of or tampering with the Test Batch?

Yes ☐ No ☐ N/A ☐

GENSAM300
Every Marijuana Cultivation Facility and Marijuana Product Manufacturing Facility must ensure that all Marijuana is placed within a sealed, tamper-evident shipping container that has no more than ten pounds of Marijuana within it prior to transport or transfer of any Marijuana to another Marijuana establishment. MTFs must document and verify the condition of the sealed package upon receipt. MTFs shall reject any Test Batch where the condition of the Test Batch at receipt indicates that the Test Batch may have been tampered with.

REFERENCES: DOR 1 CCR 212-3 5/6-410(E); 5/6-445(2); 3-1010(A)

Comments: _____

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GENSAM400
Does the laboratory document the condition and amount of Test Batch provided at the time of receipt?

Yes ☐ No ☐ N/A ☐

GENSAM400
Upon receipt, the MTF shall ensure that the Marijuana or Marijuana Product received are as described in the transport manifest and shall immediately adjust its records to reflect the receipt of inventory. The scale used to weigh product being received shall be certified in accordance with measurement standards established in Article 14 of Title 35, C.R.S. Entries to the inventory records shall note the inventory tracking System-generated transport manifest and shall be easily reconciled, by product name and quantity, with the applicable transport manifest.
Therefore, the following information should be verified and documented upon receipt of a Test Batch:

- Amount (total weight of received Test Batch(s), volume, serving size, number of items)
- Condition of integrity seals
- Anything out of the ordinary regarding the Test Batch condition

Comments: _____

_____

_____

GENSAM500
Does the laboratory document all persons handling the original Test Batches, aliquots, and extracts?

Yes ☐ No ☐ N/A ☐

GENSAM500
A MTF must establish a system to document the complete chain of custody for Test Batches, from receipt to disposal.

The laboratory should record all person(s) in custody of the Test Batch from receipt in the laboratory through analysis, storage, and disposal.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(9); 5/6-445(A)(4)

Comments: _____

GENSAM600
Does the laboratory document all transfers of Test Batches/laboratory samples, aliquots, and extracts referred to another certified Marijuana Testing Facility Licensee for additional testing or whenever requested by a client?

Yes ☐ No ☐ N/A ☐

GENSAM600
Certified laboratories may transfer Test Batches/laboratory samples, to another certified laboratory (for additional testing or upon request) by a client or the Division. A laboratory must have internal documentation of chain of custody for the transfer and the laboratory's storage inventory.

REFERENCES: DOR 1 CCR 212-3 5/6-445(A)(5)

Comments: _____

GENSAM700
Does the laboratory maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized?

Yes ☐ No ☐ N/A ☐

GENSAM700
The list of authorized personnel must indicate those with laboratory access and access to restricted areas (e.g., the laboratory may restrict access to Test Batch/laboratory samples storage to authorized individuals only; this level of authorization should be indicated). This can be documented by a list or organization chart as examples.

REFERENCES: DOR 1 CCR 212-3 3-205(B)(1-5); 5/6-415(C)(8); 5/6-445(A)(6)

Comments: _____

GENSAM800
Is the laboratory secured during non-working hours?

Yes ☐ No ☐ N/A ☐

GENSAM800
The laboratory secured during non-working hours.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(8); 5/6-445(A)(9)

Comments: _____

GENSAM900
Does the laboratory secure short and long-term storage areas when not in use?

Yes ☐ No ☐ N/A ☐

GENSAM900
A MTF must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(8); 5/6-445(A)(8)

Comments: _____

GENSAM1000
Does the laboratory utilize a secured area to log-in and aliquot Test Batches?

Yes ☐ No ☐ N/A ☐

GENSAM1000

The lab has a secured area to log-in and aliquot Test Batches.

REFERENCES: DOR 1 CCR 212-3 5/6-445(A)(9)

Comments: _____

GENSAM1100
Does the laboratory ensure Test Batches/laboratory samples are stored appropriately as defined in the written SOP?

Yes ☐ No ☐ N/A ☐

GENSAM1100
A MTF must store Test Batches/laboratory samples in the location(s) and at the temperature(s) specified in the written procedures.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A); 5/6-445(A)(10)

Comments: _____

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GENSAM1200
Does the laboratory document the disposal of Test Batches, aliquots, and extracts?

Yes ☐ No ☐ N/A ☐

GENSAM1200
A Marijuana Testing Facility must establish an adequate chain of custody and Test Batch handling instructions that must include:

- Documentation of the disposal of Test Batches
- Documentation of the disposal of aliquots
- Documentation of the disposal of extracts

The disposal documentation should include when disposal occurred, who conducted it, and how the material was disposed.

All marijuana waste must be weighed before leaving a MTF. A MTF is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana.

REFERENCES: DOR 1 CCR 212-3 5/6-415; 5/6-445(A)(11); 3-230(G);(H)(1)(2)(3)

Comments: _____

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Record Retention:

MTFs must maintain records so that analytical activities performed can be accounted. Records management is the process by which an organization manages all aspects of records, whether internally or externally generated and in any format or media type, from their creation through their lifecycle to their eventual disposal. Laboratory records provide evidence of actions and decisions and represent a vital asset to support daily functions and operations.

GENREC100
Has the laboratory established written processes to preserve books and records onsite for a minimum of six months and to maintain all records for the current calendar year and for three subsequent years?

Yes ☐ No ☐ N/A ☐

GENREC100
The laboratory must have a record retention policy in which records for at least the preceding six months are retained onsite and older records are retained either onsite or offsite for the remainder of the current year and three preceding calendar years. Virtual separation of medical and retail records must be maintained. The laboratory must maintain the following:

- Test results
- Quality Control and Quality Assurance records
- Standard operating procedures (SOPs) - All standard operating procedures as required by 1 CCR 212-3 3-905, including up-to-date records of employee training, as follows
  a. Identification of required training of employees;
  b. Documentation of training topic, training method, date of initial training, date of any necessary re-training, name and signature of trainer, and name and signature of employee;
- Personnel records
- Chain of Custody records (COC)
- Proficiency testing records (PT)
- Analytical data to include printouts generated by the instrument
- Digital photographs of each Test Batch.
- Any delegation of responsibilities from the laboratory director to a qualified supervisory analyst as permitted by Rule 5-240(B)9 or 6-240(B).

REFERENCES: DOR 1 CCR 212-3 5/6-450(B); 5/6-450; 3-905 (A)(3);(B)(12)(b,c); (B)(16)

Comments: _____

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GENREC200
Has the laboratory established a system to ensure records are adequately protected from loss or destruction?

Yes ☐ No ☐ N/A ☐

GENREC200
The laboratory must have a system through which records are protected from loss such as electric backup of paper records or separately stored redundancies of electronic records.

Comments: _____

_____

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Reporting:

Proper laboratory reporting is essential to protecting public health. Results and interpretations must be conveyed to customers so they can be applied to their products. Adequate reporting to MED is necessary so any public health hazards can be addressed and mitigated.

GENREP100
Does the laboratory adequately document the available external chain of custody information?

Yes ☐ No ☐ N/A ☐

GENREP100
The laboratory should review manifests to ensure accurate and complete external chain of custody was documented and ensure this information is accurately included in the final report.

REFERENCES: 1 CCR 212-3 5/6-415(C)(9); 5/6-445(A)(1-11); 3-825(B); 3-605(I)(2)(3)

Comments: _____

GENREP200
Does the laboratory provide the final report to the submitting client within the published turnaround time?

Yes ☐ No ☐ N/A ☐

GENREP200
The laboratory must provide the final report to submitting clients in a "timely manner". Evidence of Compliance:

- Fax transmittal record
- E-mail documentation
- Etc.

REFERENCES: DOR 1 CCR 212-3 5/6-415 (C)(9); 5/6-445(A)(1-11); 3-825(B); 3-605(I)(2)(3)

Comments: _____

GENREP300
For Industrial Hemp Test Batches, does the laboratory provide the final report to the submitting client and the Colorado Department of Agriculture?

Yes ☐ No ☐ N/A ☐

GENREP300
In accordance with section 35-61-105.5, C.R.S., a Marijuana Testing Facility shall provide the results of any testing performed on Industrial Hemp to the person submitting the Test Batch of Industrial Hemp and to the Colorado Department of Agriculture.

REFERENCES: DOR 1 CCR 212-3 6-405(E)(5)

Comments: _____

GENREP400
Does the laboratory ensure that final reports contain all pertinent information?

Yes ☐ No ☐ N/A ☐

GENREP400
The laboratory's reports must, at minimum, contain:

- MTF Licensee name and location
- Test Batch name and unique identifier
- Test Batch received date
- Report date
- Type of Test Batch tested
- Test result
- Units of measure
- Submitting client
- A dedicated area to include any qualifiers or comments needed for interpretation, (when applicable to the test method and results being reported) to include any identified and documented discrepancies

REFERENCES: DOR 1 CCR 212-3 3-825(B)(5)

Comments: _____

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GENREP500
Does the laboratory ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results?

Yes ☐ No ☐ N/A ☐

GENREP500
Scientific results can be confusing, misunderstood, or challenged by clients. It is required that the laboratory's contact information is available on the report for the clients to obtain consultation for interpretation or questions regarding quality of test results reported.

REFERENCES: DOR 1 CCR 212-3 5/6-420(C)(13)

Comments: _____

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GENREP600
Does the laboratory notify the Regulated Marijuana Business and the MED if a test batch is found to contain contaminants that could be injurious to human health if consumed?

Yes ☐ No ☐ N/A ☐

GENREP600
The laboratory must report a test batch as having failed contaminant testing if testing identifies:

- Levels of any chemical that could be toxic if consumed
- Levels of any microbial that could be toxic if consumed
- Levels of any mold, mildew, or filth that could be toxic if consumed
- Levels of other contaminants that could be injurious to human health if consumed

The Regulated Marijuana Testing Facility must notify the Regulated Marijuana Business and the MED and initiate corrective actions with all parties.

A Regulated Marijuana Testing Facility must notify the MED by timely input in the Inventory Tracking System if a Test Batch is found to contain levels of a contaminant not listed within this Rule that could be injurious to human health if consumed.

REFERENCES: DOR 1 CCR 212-3 4-115(D)(6)(7)

Comments: _____

GENREP700
Does the laboratory notify CDPHE if a test batch is found to contain STEC and Salmonella?

Yes ☐ No ☐ N/A ☐

GENREP700
The Medical Marijuana Testing Facility or Retail Marijuana Testing Facility shall contact the Colorado Department of Public Health and Environment when STEC and Salmonella are detected beyond the acceptable limits.

REFERENCES: DOR 1 CCR 212-3 4-115(D)(1)

Comments: _____

GENREP800
Does the laboratory notify MED if a test batch is found to contain contaminants that could be injurious to human health if consumed?

Yes ☐ No ☐ N/A ☐

GENREP800
The laboratory must report a test batch as having failed contaminant testing if testing identifies:

- Levels of any chemical that could be toxic if consumed
- Levels of any microbial that could be toxic if consumed
- Levels of any mold, mildew, or filth that could be toxic if consumed
- Levels of other contaminants that could be injurious to human health if consumed

REFERENCES: DOR 1 CCR 212-3 4-115(D)(6)

Comments: _____

Standards of Certification:

A Marijuana Testing Facility must meet standards of performance, as established by MED rules, in order to obtain and maintain certification.

GENCRT100
Is the Marijuana Testing Facility accredited under the International Organization for Standardization/ International Electrotechnical Commission ISO/IEC17025:2005, or any subsequent superseding ISO/IEC 17025 standard?

Yes ☐ No ☐ N/A ☐

GENCRT100
A Marijuana Testing Facility must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2005 Standard, or any subsequent superseding ISO/IEC 17025 standard.

Subsequent to initial approval of a Marijuana Testing Facility License, the MED may grant provisional certification if the Applicant has not yet obtained ISO/IEC 17025:2005 accreditation, but meets all other requirements. Such provisional certification shall be for a period not to exceed twelve months.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(2)(a)

Comments: _____

GENCRT200
Does the ISO 17025:2005 (or any subsequent superseding ISO/IEC 17025 standard) scope of accreditation specify each particular testing category?

Yes ☐ No ☐ N/A ☐

GENCRT200
In order to obtain certification in a testing category from the Division MED, the Marijuana Testing Facility's scope of accreditation must specify that particular testing category and associated methods.

REFERENCES: DOR 1 CCR 212-3 5/6-415(C)(2)(b)

Comments: _____

Colorado Department of Public Health and Environment
Laboratory Services Division
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Revision 8.0

COLORADO

Department of Public Health & Environment

Pesticide Audit Checklist for Marijuana Testing Facilities

Introduction

The Colorado Department of Public Health and Environment (CDPHE) **Pesticide Audit Checklist for Retail and Medical Marijuana Testing Facilities** (MTFs) serves as guidance and assistance to laboratories as they seek certification in the relevant category; additionally, the document reflects the rules and regulations applied by the auditors to determine if MTFs are adequately satisfying rules set forth by the Colorado Department of Revenue's (CDOR) Marijuana Enforcement Division (MED) to analyze retail marijuana and marijuana derived products. These guidelines are reflective of 1 CCR 212-3 and industry standards.

The objective of this document is to provide prospective MTFs with the same descriptions provided to the CDPHE auditors in determining precisely whether or not a MTF, or prospective MTF, adequately satisfies the requirements of MED.

CDPHE strongly recommends that MTFs utilize this document when seeking certification to assist in formulating and editing of documents and policies to satisfy requirements set forth by MED and prior to requesting site visits by CDPHE auditors. The MTF should have a large majority of the rules satisfied, prior to requesting site visits, in order for auditors to provide the MTF with the best service when seeking certification.

REQUIRED DOCUMENTATION
This section lists the documentation that the MTF must provide as evidence that it is in conformity with the requirement.

GUIDANCE
This section provides guidance specific to the required documentation. The purpose is to provide MTFs with the assistance they may need to develop the criteria that is required to obtain certification. Also, this section may describe the necessity for the documentation, procedure, policy, etc. that is being assessed. Types of materials may be described, e.g., SOPs, record retention policies, analytical data, etc.

Examples may be provided here.

For the purpose of clarity, the term "Test Batch" is used as the whole client sample package received by the laboratory.

The term "laboratory sample" or "sample" is the sub-sample (smaller sample) the laboratory takes or extracts from the whole "Test Batch" (total amount submitted) for the purpose of testing.

This section will assist the MTFs in determining what should be included in required documents, so they can satisfy the criteria set forth.

Evidence of Compliance:

- This section lists what the documents should contain, or
- This section lists what documents, in combination, satisfy the requirements

Yes ☐ No ☐ N/A ☐

REFERENCES: THIS IS WHERE THE REFERENCED RULE OR LINK TO AN INDUSTRY STANDARD WILL BE DISPLAYED

Comments: This is the comment section. This may be used by auditors to make notes regarding their findings while doing inspections. MTFs can use this section to make their own notes when applying the checklist to determine if they are ready to request an inspection by CDPHE.

Standard Operating Procedure:

SOPs provide operational guidelines and tools for companies and organizations to ensure that their products and services consistently meet customer's requirements, and that quality is consistently maintained and improved. (ISO 9000 Quality Management)

PSTSOP100
Does the laboratory's Standard Operating Procedure (SOP) Manual include the theory and principles behind each assay?

Yes ☐ No ☐ N/A ☐

PSTSOP100
Method theory and principles provide the framework for why a method is utilized and how it is applicable.

Evidence of Compliance:
Method applicability should be included as well as a description of the theory behind the instrumentation and analytical technique. Typically, the importance of detecting the target is also described.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(11)

Comments: _____

PSTSOP200
Does the SOP Manual include criteria for the preparation and identification of reagents, solutions, standards, calibrators, and controls?

Yes ☐ No ☐ N/A ☐

PSTSOP200
The procedure must include the identity of, and preparation instructions, for all materials necessary for the successful completion of the method.

The laboratory should outline the preparation of any material that does not come as working stock (i.e., eluents, matrix blanks, spiked controls, etc.)

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(12)

Comments: _____

PSTSOP300
Does the SOP Manual include criteria for special requirements and safety precautions involved in performing assays?

Yes ☐ No ☐ N/A ☐

PSTSOP300
The laboratory must have a safety manual, procedure, or policy in place, and must specify any safety requirements/precautions unique to the assay(s) used.

Evidence of Compliance:
The laboratory has described safety precautions in the appropriate SOPs, safety or quality manual, or policy. For any highly toxic chemical used in the assay, the specific precautions should be directly stated in the SOP.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(13)

Comments: _____

PSTSOP400
Does the SOP Manual include criteria for the frequency and number of control and calibration materials?

Yes ☐ No ☐ N/A ☐

PSTSOP400
The pesticide SOP and any associated extraction SOPs must outline the number of controls and calibrators required for the method, as well as control and calibration frequency. At a minimum, controls and calibration should be completed at the frequency outlined in the quality assurance and quality control section of this document (PSTQCM).

Evidence of Compliance:
- SOPs clearly articulate the required method controls and the frequency of analysis.
- SOPs clearly articulate the required calibrators and the frequency of analysis.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(14)

Comments: _____

PSTSOP500
Does the SOP Manual include criteria for recording and reporting assay results?

Yes ☐ No ☐ N/A ☐

PSTSOP500
The laboratory reports for pesticide testing should include all information described in GENREP300 in the CDPHE General Audit Checklist and in the Reporting section of this document. The SOP should outline, in detail, the recording of results and reporting results to clients, as well as the entry of results into the METRC data system.

All test results must be reported in METRC as part of daily reconciliation by the close of business.

REFERENCES: DOR 1 CCR 212-3 5/6-425(15)

Comments: _____

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PSTSOP600
Does the SOP Manual include pertinent literature references for each method?

Yes ☐ No ☐ N/A ☐

PSTSOP600
Literature references must be peer-reviewed if not published by a government agency. For a nonexclusive list of appropriate references, see the CDPHE Marijuana Testing Reference Library.

Applicable references may include, but are not limited to:

- Association of Analytical Communities (AOAC) 2016. "Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning with Magnesium Sulfate, 2007.01" http://www.eoma.aoac.org/methods/info.asp?ID=48938
- Determination of Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning with Magnesium Sulfate: Collaborative Study LEHOTAY: Journal of AOAC International Vol.90,No.2,2007.
- Food and Drug Administration (FDA), 2016: Pesticide Analytical Manual (PAM).

REFERENCES: DOR 1 CCR 212-3 5/6-425(17)

Comments: _____

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PSTSOP700
Do laboratory SOPs include step-by-step instructions with sufficient detail to perform the assay, to include equipment operation and any abbreviated versions used by a testing analyst?

Yes ☐ No ☐ N/A ☐

PSTSOP700
SOPs must contain detailed descriptions of how to perform a task, so an employee may perform the task in the same manner every time.

Evidence of Compliance:
SOPs include:

- Materials/equipment list and equipment parameters.
- Any pre/post-analytical cleaning.
- Instructions for making/procuring/utilizing method materials.
- Procedural operations, such as Test Batch/laboratory sample preparation and analysis.
- Applicable calculations

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(18)

Comments: _____

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PSTSOP800
Does the SOP Manual include acceptability criteria for the results of controls?

Yes ☐ No ☐ N/A ☐

PSTSOP800
Acceptability criteria for all calibration and QC materials (e.g., controls, spikes, blanks, etc.) must be defined, as well as the action to be taken when results are outside satisfactory control limits. When possible, acceptability criteria should be determined using testing data to establish statistically valid control ranges for each procedure. Acceptability criteria must not be too loosely defined or set in a manner that could jeopardize the integrity of the result.

Evidence of compliance:

- Clearly defined acceptance criteria, quality control tracking procedures, and protocols for corrective actions.

REFERENCES: DOR 1 CCR 212-3 6-425(A)(19)

Comments: _____

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PSTSOP900
Does the laboratory SOP manual include acceptability criteria for variances between different aliquots and different columns?

Yes ☐ No ☐ N/A ☐

PSTSOP900
The laboratory must define acceptability criteria for the allowable variance between aliquots, duplicates, and new standard lots and when major maintenance/changes occur, such as replacing a column or switching column types.

Repeatability and precision assessment should be calculated and reported as relative percent difference between two aliquots (e.g., duplicate laboratory samples).

REFERENCES: CLINICAL LABORATORY IMPROVENT AMENDMENTS (CLIA) §493.51; DOR 1 CCR 212-3 5/6-425(A)(19)

Comments: _____

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PSTSOP1000
Does the SOP Manual include a documented system for reviewing the results of controls, standards, and test results?

Yes ☐ No ☐ N/A ☐

PSTSOP1000
The SOP manual must describe a procedure for the review of all analytical data. See GENSOP1300 in the CDPHE General Audit Checklist for additional guidance.

Evidence of compliance:

- Documented review of the analysts maintaining/setting up/performing lot checks of standards and controls (bench sheets, employee competency, training records, etc.).
- Documented review of Test Batch/laboratory samples preparation records.
- Documented primary and secondary review (all analytical data must be reviewed by two separate reviewers for errors and remediated prior to accepting/rejecting results).

REFERENCES: GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL EPA/600/B-07/001
DOR 1 CCR 212-3 5/6-425(A)(20)

Comments: _____

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PSTSOP1100
Does the SOP Manual include a documented system of reviewing for clerical errors, analytical errors, and any unusual analytical results?

PSTSOP1100
The SOP Manual must describe a procedure for review of routine/daily testing, including how review is to be documented. Review must be documented to reflect that each analytical result reported has been evaluated as required by the SOP.

Evidence of compliance (including, but not limited to):

- Documented review of results (ensure that test results are reported in the proper units, for the proper Test Batches/laboratory samples, and that samples and control results meet all of the aforementioned checks and balances).
- Documented review of transcribed data to prevent errors in data entry (this may include results, client information, etc.).
- Documented review of unusual analytical results (co-eluting peaks, peak tailing or fronting, baseline wander and drift, etc.)
- Documented review of analytical errors (incorrect calculations, dilution factors, etc.)

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(20)
GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL EPA/600/B-07/001

Comments: _____

Validations:

In order to have confidence in laboratory methodology, certain criteria must be established, met and shown to be consistent. The application of parameters applied during method validation, allow for the general acceptance of data generated during analysis.

COLORADO
Department of Public Health & Environment

PSTVAL100
Has the laboratory validated the method following good laboratory practices prior to reporting results?

Yes ☐ No ☐ N/A ☐

POVAL100
Validations of new methodologies/platforms must include, when applicable, but are not limited to:

- Accuracy
- Precision
- Analytical sensitivity
- Analytical specificity
- Limit of Detection (LOD)
- Limit of Quantification (LOQ)
- Linearity/Reportable Range
- Recovery
- Repeatability
- Identification of interfering substances

The fundamental parameters for proper validation include those listed. Method validation documentation must be maintained by the laboratory, which includes, but is not limited to, the raw analytical data and a validation report containing sufficient information that the study could be repeated. Identification of matrix effects must occur during pesticide method development/validation. The following steps can reduce matrix interference.

- Extraction clean-up: selectively remove interferences during the laboratory sample preparation stage (dSPE, cartridge SPE, Filtration, other).
- Chromatographic: physically separate the analyte and interference on column so they elute at different times.
- Matrix matching: the process of ensuring that all standards, quality control (QC) samples and laboratory samples are in an identical matrix so that any ion suppression is constant.

Software must be validated prior to testing Test Batches, including but not limited to:

- analytical software.
- application programming interface(s) (APIs).
- laboratory information management systems (LIMS), etc.

Minimum compliance:

- To demonstrate accuracy, the laboratory must include at least five independent analyses per concentration level.
- Replicate analysis should include data from a minimum of two days where the number of replicates and test portions is at least greater than ten.
- The laboratory must establish the method LOQ (MLOQ) defined as the lowest value that can be quantified with at least 95% confidence.

REFERENCES: DOR 1 CCR 212-3 5/6-430(I)

Comments: _____

PSTVAL200
Has the laboratory documented the validation of all methods including new methodology?

Yes ☐ No ☐ N/A ☐

PSTVAL200
The laboratory should present validation data in a well formatted document, styled after peer-reviewed scientific publications, that includes sufficient information so that an experienced analyst could repeat the validation study. A validation report must accompany the raw data and should include, but need not be limited to:

- Validation plan.
- Introduction and brief summary.
- Materials and preparation methods.
- Method parameters.
- Chromatograms, calculations and results.
- Method acceptance limit performance data.
- Instrument calibration data, if any.
- Conclusion and discussion.
- References.

REFERENCES: DOR 1 CCR 212-3 5/6-430(I)(2)

Comments: _____

PSTVAL300
Has the laboratory validated or revalidated any new or revised methodology approved for use by the laboratory director prior to testing Test Batches?

Yes ☐ No ☐ N/A ☐

PSTVAL300
Any changes to an approved methodology must be revalidated as appropriate. If the laboratory makes significant changes to the approved method, the method must be revalidated and provided to CDPHE.
A method validation or revalidation is required for the following:

- Submission of a new or original method.
- Expansion of the scope of an existing validated method.
- Modification of the range of the method beyond validated levels.
- Modifications which alter the method's performance specifications such as fundamental technology, reagents, instrumental parameters, or Test Batch/laboratory sample preparation, treatment, or extraction.

REFERENCES: DOR 1 CCR 212-3 5/6-430(I)(2)(3)

Comments: _____

PSTVAL400
Has the laboratory, at a minimum, validated all state mandated matrices in accordance with **1 CCR 212-3 4-115(D), 6/5-430(J)?**

Yes ☐ No ☐ N/A ☐

PSTVAL400
The laboratory must validate the following matrices:

- Regulated Marijuana flower, shake, trim, and wet whole plant; Physical Separation- Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Medical Marijuana Concentrate; Physical Separation- Based, Food-Based, Heat/Pressure-Based, and Solvent-Based Retail Marijuana Concentrate; Pre-Rolled Marijuana; Infused Pre-Rolled Marijuana; Industrial Hemp Product

Testing and Validation of Complex Matrices. A Retail/Medical Marijuana Testing Facility must include a variety of matrices as part of the validation/verification process. During method validation/verification, a Marijuana Testing Facility must:

- Select matrices which best represent each category of products to be tested as listed in Rule 4-115(D). The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, cannabinoid content, pH, salt content, sugar content, water activity, the presence of know chemical compounds, microbial flora and antimicrobial compounds.

REFERENCES: DOR 1 CCR 212-3 4-115(D)(1);4-135(C)(5);5/6-430(I)(1) ;5/6-430(J)(1)

Comments: _____

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PSTVAL500
Has the laboratory performed a new matrix validation, prior to reporting results, on matrices which are either a new category of matrix or are considerably different from the original matrix validated within the category?

Yes ☐ No ☐ N/A ☐

PSTVAL500
The laboratory must fully ensure method fitness for any newly encountered matrix which was not included in the initial validation. For example, the Retail/Medical Marijuana Testing Facility intends to receive the topical product “bath bombs” for testing, but previous validation studies for topical product included lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.

REFERENCES: DOR 1 CCR 212-3 5/6-430(J)(2)

Comments: _____

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PSTVAL600
Has the laboratory performed a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated but which fall within a category already validated?

Yes ☐ No ☐ N/A ☐

PSTVAL600
The laboratory must ensure method fitness for any matrix encountered which, while included in the initial validation, differs in some major way. For example, the Retail/Medical Marijuana Testing Facility laboratory receives a new edible type matrix for testing (snickerdoodle cookies) but previous validation included gummies and hard candy. A spike of a portion of the submitted material must be analyzed prior to, or at the time of, laboratory sample analysis.

REFERENCES: DOR 1 CCR 212-3 5/6-430(J)(3)

Comments: _____

PSTVAL700
Has the laboratory established a written SOP for new or revised methodologies that is approved, signed, and dated by the Laboratory Director prior to use?

Yes ☐ No ☐ N/A ☐

PSTVAL700
The Laboratory Director must approve, sign, and date all SOPs. All updated SOPs or re-validated methods must be approved and signed by the current laboratory director prior to use.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(7)

Comments: _____

PSTVAL800
Has the laboratory, at a minimum, validated for an appropriate range of concentration levels of Abamectin (Avermectins: B1a & B1b, Azoxystrobin, Bifenazate, Etoxazole, Imazalil, Imidacloprid, Malathion, Myclobutanil, Permethrin (mix of isomers), Spinosad (Mixture of A and D), Spiromesifen, Spirotetramat, Tebuconazole as stated in **DOR 1 CCR 212-3 4-115 (D)(5)(a)?**

Yes ☐ No ☐ N/A ☐

PSTVAL800
Laboratory methodologies must demonstrate, through validation, the capability of detecting an applicable range of the 105 stated pesticides.

Effective **July 1, 2023,** the following pesticides will be subject to required testing, at the associated action limits:

- Abamectin (Avermectins B1a & B1b), Azoxystrobin, Bifenthrin, Bifenazate, Boscalid, Carbaryl, Chlorpyrifos, Clothianidin, Diuron, Etoxazole, Imazalil, Imidacloprid, Malathion, Metalaxyl, Myclobutanil, Permethrins, Propiconazole, Pyriproxyfen, Spinosad, Spriomesifen, Spirotetramat, Tebuconazole, Thiabendazole, Thiamethoxam.

Effective **July 1, 2024,** the following pesticides will be subject to required testing, at the associated action limits:

- Abamectin (Avermectins B1a & B1b), Acephate, Acequinocyl, Acetamiprid, Aldicarb, Allethrin, Atrazine, Azoxystrobin, Benzovindiflupyr, Bifenazate, Bifenthrin, Boscalid, Buprofezin, Carbaryl, Carbofuran, Chlorantraniliprole, Chlorphenapyr, Chlorpyrifos, Clofentezine, Clothianidin, Coumaphos, Cyantraniliprolem Cyfluthrin, Cyhalothrin lambda, Cypermethrin, Cyprodinil, Daminozide, Deltamethrin, Diazinon, Dichlorvos, Dimethoate, Dimethomorph, Dinotefuran, Diuron, Dodemorph, Endosulfan sulfate, Endosulfan-alpha, Endosulfan-beta, Ethoprophos, Etofenprox, Etoxazole, Etridiazole, Fenhexamid, Fenoxycarb, Fenpyroximate, Fensulfothion, Fenthion, Fenvalerate, Fipronil, Flonicamid, Fludioxonil, Fluopyram, Hexythiazox, Imazalil, Imidacloprid, Iprodione, Kinoprene, Krosoxim-methyl, Malathion, Metalaxyl, Methiocarb, Methomyl, Methoprene, Mevinphos, MGK-264, Myclobutanil, Naled, Novaluron, Oxamyl, Paclobutrazol, Parathion-methyl, Permethrins, Phenothrin, Phosmet, Pirimicarb, Prallethrin, Propiconazole, Propoxur, Pyraclostrobin, Pyridaben, Pyriproxyfen, Quintozene, Resmethrin, Spinetoram, Spinosad, Spirodiclofen, Spriomesifen, Spirotetramat, Spiroxamine, Tebuconazole, Tebuenozide, Teflubenzuron, Tetrachlorvinphos, Tetramethrin, Thiabendazole, Thiacloprid, Thiamethoxam, Thiophanate-methyl, Trifloxystrobin.

REFERENCES: DOR 1 CCR 212-3 4-115; 3-335 (K); 4-125(A)(2)

Comments: _____

PSTVAL900
Has the laboratory, when required, performed a proper verification of a previously validated method?

PSTVAL900

The laboratory shall perform a method verification for validated methods when there is change in testing location or the method is being adopted on a new instrument/platform.

Verification must include, when applicable, but is not limited to:

- Accuracy
- Precision
- Limit of Detection (LOD)
- Limit of Quantification (LOQ)
- Specificity (Only if different instrument sensitivity affects specificity)

The laboratory must verify method accuracy across the concentration range (if applicable, where concentration is greater than one order of magnitude) for which the laboratory intends to test, i.e., low, medium and high concentrations. Laboratories must demonstrate precision by performing a repeatability test at least once covering the range of concentrations for which the method is designed (if applicable, where concentration is greater than one order of magnitude).

LOD and LOQ must be verified through analysis of sample spikes at or close to the stated method LOD and LOQ.

In cases in which laboratory instrumentation differs from the instrumentation listed in the published standard method, the laboratory must verify specificity in matrix.

Yes ☐ No ☐ N/A ☐

REFERENCES: AOAC/ALACC 2007 Guide "How to Meet ISO 17025 Requirements for Method Verification"

Comments: _____

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_____

Analytical Processes:

High Performance Liquid Chromatography (HPLC) & Liquid Chromatography Mass Spectroscopy (LC-MS)

The analytical process can be described as consisting of four principle stages of operation:

1. Sampling
2. Isolation/separation of the desired constituent
3. Measurement/detection of the desired constituent
4. Calculation and interpretation of the data

P. J. Elving, *Anal. Chem.*, **1950**, 22 (8), pp 962–965 **DOI:** 10.1021/ac60044a002
Publication Date: August 1950

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PSTLCM100
Does the laboratory perform and document routine and preventative maintenance as required by the manufacturer or SOP?

Yes ☐ No ☐ N/A ☐

PSTLCM100
Routine preventative maintenance works to ensure that the instrument is kept in good condition and may assist in identifying potential problems. Maintenance operations are performed periodically to lessen the likelihood of instrument failure. If routine and preventative maintenance are not prescribed by the instrument manufacturer, the laboratory must establish its own maintenance requirements and schedule.

Evidence of compliance:

- Documentation of maintenance activities and instrument performance after maintenance.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(1)

Comments: _____

PSTLCM200
Does the laboratory evaluate the performance of the instrument when changes in source, conditions, detector, eluent, or column are made prior to reporting test results?

Yes ☐ No ☐ N/A ☐

PSTLCM200
The laboratory shall evaluate and document the performance of the instrument after routine and preventative maintenance, as well as after major changes such as column replacement, eluent replacement, pump maintenance, etc. Should quality data show deviation from the defined acceptance criteria, the laboratory must issue corrective actions to evaluate the problem and come to a resolution prior to reporting results.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(9)

Comments: _____

PSTLCM300
Does the laboratory monitor and document the performance of the LC/MS instrument each day of testing?

Yes ☐ No ☐ N/A ☐

PSTLCM300
The laboratory must establish and implement acceptability criteria for system suitability. This must include, but need not be limited to:

- Verification of system pressure
- Verification of acceptable tune parameters
- Verification of passing quality controls (retention time match, accurate quantitation of each analyte, etc.)

The laboratory must ensure and document that the instrument performs properly each day of testing. Should quality data show deviation from set acceptability criteria, the laboratory must issue corrective actions to evaluate the problem and come to a resolution prior to reporting results.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(6)

Comments: _____

PSTLCM400
Does the laboratory maintain records of mass spectrometric tuning?

Yes ☐ No ☐ N/A ☐

PSTLCM400
The laboratory must keep records of mass spectrometric tuning and must perform tunes at a relevant frequency set by the laboratory. At a minimum, the laboratory should tune the mass spectrometer at the frequency specified by the manufacturer. Documentation must include the criteria whereby tuning procedures are deemed to be acceptable.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(3)

Comments: _____

PSTLCM500
Does the laboratory document corrective actions if a mass-spectrometric tune is unacceptable?

Yes ☐ No ☐ N/A ☐

PSTLCM500
The laboratory must establish and implement criteria to monitor the spectrometric tuning requirements. If a tune is unacceptable, corrective actions must be taken and documented to address and correct the failure(s).

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(4)

Comments: _____

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PSTLCM600
Does the laboratory document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument?

Yes ☐ No ☐ N/A ☐

PSTLCM600
The laboratory shall document and maintain records after major changes such as, but not limited to, column replacement, source change, instrument parameter adjustment, and eluent replacement.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(8); 212-3 5/6-430(F)(9)

Comments: _____

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PSTLCM700
Does the laboratory document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system?

Yes ☐ No ☐ N/A ☐

PSTLCM700
Monitoring of internal standard response is an important component of analytical run review. Any individual irregularities or gradual trends in internal standard response can indicate discrepancies in actual injection volume between injections, variability in instrument performance, or analyte response due to matrix affects. Documented monitoring can aid in identification of these issues and guide subsequent investigation and corrective actions.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(6)

Comments: _____

PSTLCM800
Does the laboratory compare two transitions and retention times between calibrators, controls and laboratory samples within each run?

Yes ☐ No ☐ N/A ☐

PSTLCM800
The laboratory shall ensure method quality by comparing transitions and retention times between controls, calibrators and laboratory samples. The laboratory must establish, based on adequate reference methods, acceptance criteria for the aforementioned comparison criteria.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(7)

Comments: _____

PSTCAL100
Does the laboratory perform and document a calibration curve with each analysis using at a minimum five calibrators throughout the reporting range?

Yes ☐ No ☐ N/A ☐

PSTCAL100
The multipoint calibration should consist of one or more measurements of the analyzer responses to at least five different concentrations (preferably seven).
The EPA guidance on this subject states that it is prohibited to remove data points from within a calibration range while still retaining the extreme ends of the calibration range. If a calibration point fails, the laboratory should re-prepare and re-analyze the calibration standard.

REFERENCES: EPA METHOD 8000C DETERMINATIVE CHROMATOGRAPHIC SEPARATIONS

Comments: _____

PSTCAL200
Are there records of the calibration of the instrument?

Yes ☐ No ☐ N/A ☐

PSTCAL200
The laboratory must maintain records of instrument calibration. Previous calibration data should be properly labeled, stored and easily accessible to analysts.

REFERENCES: DOR 1 CCR 212-3 5/6-450(B)(7)

Comments: _____

PSTCAL300
If the initial calibration is not performed on the day of analysis, is it possible to trace back directly to the initial calibration?

Yes ☐ No ☐ N/A ☐

PSTCAL300
It is important the calibration data is traceable and recoverable. The calibration used for any individual analysis must be captured in the laboratory records.

REFERENCES: DOR 1 CCR 212-3 5/6-450(B)(7)

Comments: _____

PSTCAL400
If an initial calibration is not performed on the day of analysis, is the calibration verified prior to the analysis of samples by an initial calibration verification?

Yes ☐ No ☐ N/A ☐

PSTCAL400
Initial Calibration Verification (ICV) should be analyzed prior to laboratory sample analysis. The ICV must be generated from a source separate from the calibration and continuing calibration verification material. The laboratory must establish acceptance criteria as relevant to the method; typically, this is evaluated as percent recovery.

% Recovery = (measured value ÷ true value)*100).

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(17); PA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN

Comments: _____

PSTCAL500
Are results derived from the initial calibration, not the continuing calibration verification?

Yes ☐ No ☐ N/A ☐

PSTCAL500
Calibration checks should only be used as verification of the initial calibration and should not be used to calculate results.

Continuing Calibration Verification (CCV) should be analyzed prior to sample analysis and every 10 – 20 laboratory samples thereafter (or after a 12-hour period, should less than 20 laboratory samples be analyzed). The CCV controls are generally created from the same source as the calibration material. The laboratory must outline acceptance criteria as relevant to the method; ideally, the CCV should fall within at least ± 15% of the spike value.

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN /001 *GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL* 212-3 5/6-430(F)(8)

Comments: _____

PSTCAL600
Does the laboratory document the calibration curve and verify that it has a correlation coefficient of 0.995 or greater?

Yes ☐ No ☐ N/A ☐

PSTCAL600

The laboratory must ensure that calibration curves fall within laboratory established limits; established limits must not fall below a correlation coefficient of 0.995.

United States Department of Agriculture – Food Safety and Inspection Service (USDA FSIS); Office of Public Health Science, 2018. *Screening, Determination and Confirmation of Beta-Agonists by LC/MS/MS*

Comments: _____

Quality Assurance & Quality Control:

Laboratory Quality Assurance Programs (QAP) encompass a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. Test results produced by MTFs have a significant influence on public health and industry product acceptability. A good QA system does *at least*:

- Establishes SOPs for each step of the laboratory testing process, ranging from specimen handling to instrument performance validation.
- Defines administrative requirements, such as mandatory recordkeeping, data evaluation, and internal audits to monitor adherence to SOPs.
- Specifies corrective actions, documentation, and the persons responsible for carrying out corrective actions when problems are identified; and
- Sustains high-quality employee performance.

(http://www.cdc.gov/labstandards/)

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PSTQCM100
Does the laboratory, for qualitative analyses, analyze, at minimum, a negative and a positive control for each analyte analyzed with each batch of laboratory samples analyzed?

Yes ☐ No ☐ N/A ☐

PSTQCM100
A qualitative positive control contains the analyte being tested; it reacts positively and demonstrates the test's ability to detect the expected analytes. A negative control does not contain the analyte being tested. It contains only the solvent or medium and demonstrates the test's ability to run without interference or contamination.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(9)

Comments: _____

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PSTQCM200
Does the laboratory, for quantitative analyses, analyze, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve?

Yes ☐ No ☐ N/A ☐

PSTQCM200
A quantitative positive control contains the analyte being tested at a known, theoretical concentration. The two levels of positive controls should challenge the low and high end of the corresponding calibration curve. Different concentrations of controls assure that a test run is valid and results are reliable throughout the whole range of the curve.

A negative or blank control should also be run to demonstrate the test's ability to run without interference or contamination.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(10)

Comments: _____

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PSTQCM300
Does the laboratory use control material(s) that differ in either source or, lot number, or concentration from the calibration material used with each analytical run?

Yes ☐ No ☐ N/A ☐

PSTQCM300
A second source of control material, different from the calibration material, should be obtained. Second source calibration verification determines if the stock and working standards are accurate.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(11)

Comments: _____

PSTQCM400
Does the laboratory, for multi-analyte assays, perform and document calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run?

Yes ☐ No ☐ N/A ☐

PSTQCM400
The multipoint calibration should consist of analyzer responses to at least five different concentrations of the analyte of interest.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(12)

Comments: _____

PSTQCM500
Does the laboratory analyze controls in the same manner as unknowns?

Yes ☐ No ☐ N/A ☐

PSTQCM500
Method controls (positive and negative) must be analyzed in the same manner as client samples. To properly assess the entire testing process, controls must pass through every part of the method, including Test Batch/laboratory sample preparation, extraction, and analysis.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(14)

Comments: _____

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PSTQCM600
Does the laboratory analyze an appropriate instrument blank, reagent blank and matrix blank with each analytical run?

Yes ☐ No ☐ N/A ☐

PSTQCM600
The laboratory must analyze an appropriate reagent blank and method/matrix blank with each analytical batch. The method blank control sample must consist of a matrix blank (flower, concentrate etc.) or surrogate matrix that adequately demonstrates similar matrix effect and extraction recovery) and must be analyzed in the same manner as Test Batches/laboratory samples (carried through the complete preparation and analytical procedure.) Typically, an instrument blank follows a positive control in the analytical sequence to ensure the absence of target analyte carryover.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(13)

Comments: _____

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PSTQCM700
Is a Matrix Spike (sample prepared by adding a known mass of target analyte to a specific amount of matrix) performed at a frequency of 1 in 20 samples, or less, per matrix type prepared over time, except for analytes for which spiking solutions are not available?

Yes ☐ No ☐ N/A ☐

PSTQCM700
The Matrix Spike is a separate aliquot of the laboratory sample spiked with known concentrations of the analytes of interest. It is analyzed to determine, including the matrix interferences, if the procedure is working within established control limits. It is carried through the complete preparation and analytical procedure.

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN

Comments: _____

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PSTQCM800
Does the laboratory document the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the Standard Operating Procedure is met?

Yes ☐ No ☐ N/A ☐

PSTQCM800
The laboratory must document the results of calibration standards and controls, and these results must be adequately reviewed to ensure acceptability prior to the reporting of results. All data review must be documented. Control charting shall be performed to facilitate identification of trends.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(15)

Comments: _____

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PSTQCM900
Is a Matrix Spike duplicate (MSD) or a laboratory duplicate performed at a frequency of at least 1 in 20 samples, or less, per matrix, per extraction or preparation method?

Yes ☐ No ☐ N/A ☐

PSTQCM900
Analyses of Matrix Spike Duplicates (MSD) or laboratory duplicates are used to evaluate analytical or measurement precision. Repeatability and precision assessment should be calculated and reported as Relative Percent Difference between aliquots of two (one duplicate per laboratory sample). Duplicate laboratory samples must be within ± 20% RPD. Relative Standard Deviation can be used to compare 3 or more replicates.

%RPD = ((|difference|)/average)*100
%RSD = (Standard deviation/mean)*100

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN

Comments: _____

PSTQCM1000
Does the laboratory document all troubleshooting and corrective actions taken when calibration, control, or standards do not meet acceptability criteria as defined in the Standard Operating Procedure?

Yes ☐ No ☐ N/A ☐

PSTQCM1000
The laboratory should document all troubleshooting and corrective actions taken when calibration, control, or standards fail to meet acceptability criteria. This documentation should be detailed and include the type of problem, the cause of the problem, the steps taken to correct the problem, and where applicable, steps taken to amend customer results. The laboratory director or delegated supervisory analyst must consistently review, sign, and date all corrective actions to ensure appropriateness and effectiveness of corrective actions.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(16) (B)(11)

Comments: _____

PSTQCM1100
Does the laboratory use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound?

Yes ☐ No ☐ N/A ☐

PSTQCM1100
Internal standard is used to monitor or improve the precision of analysis. An internal standard is a known concentration of a substance that is present in every laboratory sample analyzed. The purpose of the internal standard is to behave similarly (e.g., ionization potential and mass) to the analyte but to provide a signal that can be distinguished from that of the analyte. This minimizes errors caused by evaporation of solvents and injection errors or discrepancies. Surrogate Standards are analytes added to a laboratory sample at a known concentration in order to determine extraction efficiency; in addition, they are chemically similar to those analytes being extracted. Surrogate standards offer better data defensibility and, when used, satisfy the internal standard requirement.

REFERENCES: DOR 1 CCR 212-3 5/6-430(E)(6)(F)(5)

Comments: _____

PSTQCM1200
Are laboratory control samples (LCS-standard of known amount prepared from a source independent of calibration standards or a material containing a known amount of analyte) analyzed at a minimum of 1 per batch of 20 or less laboratory samples per matrix type, per extraction or preparation method?

Yes ☐ No ☐ N/A ☐

PSTQCM1200
Laboratory control samples are used to demonstrate that the laboratory is in control of the processes involved in the preparation and analysis of specific tests. It is critical that the laboratory be able to not only accurately recover the target analytes, but also to be able to reproduce that action. A Laboratory Control Sample Duplicate (LCSD) can be used to demonstrate repeatability.

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN

Comments: _____

PSTQCM1300
If there are manual integrations performed, are records maintained to recreate the manual integration?

Yes ☐ No ☐ N/A ☐

PSTQCM1300
Generally, chromatographic peaks generated will be integrated using automated methods by the software provided by the instrument manufacturer. It may be necessary for an analyst to review the automated integration, make adjustments and manually integrate the peaks. The principles and the specific procedures for completing, documenting and reviewing manual integration must be applied consistently to ensure defensible integrations. Essential information associated with laboratory sample analysis including all information necessary for the reconstruction of the data must be maintained; this includes manual integration performed in accordance with the laboratory SOP.

Manual Integration - The NELAC Institute
www.nelac-institute.org/docs/meetings/newport2008/manual_integration_080115.pdf

Comments: _____

PSTQCM1400
Do the records include the identification of any standards, internal standards, solvents, etc. used in the analysis and preparation of the Test Batches/laboratory sample?

Yes ☐ No ☐ N/A ☐

PSTQCM1400
Tracking of standards, internal standards, solvents, reagents, etc. throughout the laboratory is an essential quality control practice. Proper traceability aids in materials accountability, defensibility of data and is a useful troubleshooting tool.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(12)

Comments: _____

Reporting:

Proper laboratory reporting is essential to regulatory compliance and good client relations, as well as protecting public health. Results and interpretations must be conveyed in a way that customers can understand. Adequate reporting to MED is necessary to ensure that any public health hazards can be addressed and mitigated.

PSTREP100
Does the laboratory report quantitative results that are only above the lowest concentration of calibrator or control standard used in the analytical run?

Yes ☐ No ☐ N/A ☐

PSTREP100
The laboratory may only report quantitative results that are above the limit of quantification (LOQ) and below the upper limit of quantification (ULOQ) and this must be specified in the laboratory SOP manual. Results below the LOQ or above the ULOQ may be reported qualitatively as described by the laboratory.

REFERENCES: DOR 1 CCR 212-3 1-115

Comments: _____

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PSTREP200
Does the laboratory verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the laboratory sample in duplicate prior to reporting a quantitative result?

Yes ☐ No ☐ N/A ☐

PSTREP200
If quantifying below the lowest concentration of calibration, the laboratory should verify by analyzing a blank and a standard (and duplicate) that falls below the expected concentration of the analyte. Results must meet the established acceptability criteria.

REFERENCES: DOR 1 CCR 212-3 3-825(B)(1))

Comments: _____

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PSTREP300
Does the laboratory qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation?

Yes ☐ No ☐ N/A ☐

PSTREP300
Results below the lowest concentration of calibrator and above the LOD must be reported as qualitative results (i.e., trace or non-specific numerical designations such as “less than the lowest calibrator”).

Results below the LOD must not be reported as “zero” as this is misleading. These results could be reported as “non-detect”, as “less than the limit of detection”, or as the measured value with the associated uncertainty.

REFERENCES: DOR 1 CCR 212-3 3-825(B)(3)-3 3-825(B)(3)

Comments: _____

References:

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2. AOAC Appendix K: Guidelines for Dietary Supplements and Botanicals
3. AOAC/ALACC 2007 Guide "*How to Meet ISO 17025 Requirements for Method Verification*"
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   https://cdphe.colorado.gov/laboratory-services/inspection-of-marijuana-testing-facilities/marijuana-reference-library
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11. EPA 903 8-91 001 *Chemical Concentration Data Near Detection Limit*
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13. (CLIA) *CLINICAL LABORATORY IMPROVENT AMENDMENTS* §493.51

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www.nelac-institute.org/docs/meetings/newport2008/manual_integration_080115.pdf

16. NIH *Guidelines on Good Clinical Laboratory Practice: Bridging Operations between Research and Clinical Research Laboratories*
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17. United States Department of Agriculture – Food Safety and Inspection Service (USDA FSIS); Office of Public Health Science, 2018. *Screening, Determination and Confirmation of Beta-Agonists by LC/MS/MS*
https://www.fsis.usda.gov/sites/default/files/media_file/2020-09/CLG-AGON1.pdf

18. Wisconsin Department of Natural Resources Section 08: Analytical Instrument Calibration
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COLORADO
Department of Public Health & Environment

Potency Audit Checklist for Marijuana Testing Facilities

Introduction

The Colorado Department of Public Health and Environment (CDPHE) **Potency Audit Checklist for Retail and Medical Marijuana Testing Facilities** (MTFs) serves as guidance and assistance to laboratories as they seek certification in the relevant category; additionally, the document reflects the rules and regulations applied by the auditors to determine if MTFs are adequately satisfying rules set forth by the Colorado Department of Revenue's (CDOR) Marijuana Enforcement Division (MED) to analyze retail marijuana and marijuana derived products. These guidelines are reflective of 1 CCR 212-3 and industry standards.

The objective of this document is to provide prospective MTFs with the same descriptions provided to the CDPHE auditors in determining precisely whether or not a MTF, or prospective MTF, adequately satisfies the requirements of MED.

CDPHE strongly recommends that MTFs utilize this document when seeking certification to assist in formulating and editing of documents and policies to satisfy requirements set forth by MED and prior to requesting site visits by CDPHE auditors. The MTF should have a large majority of the rules satisfied, prior to requesting site visits, in order for auditors to provide the MTF with the best service when seeking certification.

REQUIRED DOCUMENTATION
This section lists the documentation that the MTF must provide as evidence that it is in conformity with the requirement.

GUIDANCE
This section provides guidance specific to the required documentation. The purpose is to provide MTFs with the assistance they may need to develop the criteria that is required to obtain certification. Also, this section may describe the necessity for the documentation, procedure, policy, etc. that is being assessed. Types of materials may be described, e.g., Standard Operating Procedures (SOPs), record retention policies, analytical data, etc.

Examples may be provided here.

For the purpose of clarity, the term "Test Batch" is used as the whole client sample package received by the laboratory.

The term "laboratory sample" or "sample" is the sub-sample (smaller sample) the laboratory takes or extracts from the whole "Test Batch" (total amount submitted) for the purpose of testing.

This section will assist the MTFs in determining what should be included in required documents, so they can satisfy the criteria set forth.

Evidence of Compliance:

- This section lists what the documents should contain, or
- This section lists what documents, in combination, satisfy the requirements

Yes ☐ No ☐ N/A ☐

REFERENCES: THIS IS WHERE THE REFERENCED RULE OR LINK TO AN INDUSTRY STANDARD WILL BE DISPLAYED

Comments: This is the comment section. This may be used by auditors to make notes regarding their findings while doing inspections. MTFs can use this section to make their own notes when applying the checklist to determine if they are ready to request an inspection by CDPHE.

Standard Operating Procedure:

SOPs provide operational guidelines and tools for companies and organizations to ensure that their products and services consistently meet customer's requirements, and that quality is consistently maintained and improved. (ISO 9000 Quality Management)

POTSOP100
Does the laboratory's Standard Operating Procedure (SOP) Manual include the theory and principles behind each assay?

Yes ☐ No ☐ N/A ☐

POTSOP100
Method theory and principles provide the framework for why a method is utilized and how it is applicable.

Evidence of Compliance:
Method applicability should be included as well as a description of the theory behind the instrumentation and analytical technique. Typically, the importance of detecting the target is also described.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(11)

Comments: _____

POTSOP200
Does the SOP Manual include criteria for the preparation and identification of reagents, solutions, standards, calibrators, and controls?

Yes ☐ No ☐ N/A ☐

POTSOP200
The procedure must include the identity of, and preparation instructions, for all materials necessary for the successful completion of the method.

The laboratory should outline the preparation of any material that does not come as working stock (i.e., eluents, matrix blanks, spiked controls, etc.)

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(12)

Comments: _____

POTSOP300
Does the SOP Manual include criteria for special requirements and safety precautions involved in performing assays?

Yes ☐ No ☐ N/A ☐

POTSOP300
The laboratory must have a safety manual, procedure, or policy in place, and must specify any safety requirements/precautions unique to the assay(s) used.

Evidence of Compliance:
The laboratory has described safety precautions in the appropriate SOPs, safety or quality manual, or policy. For any highly toxic chemical used in the assay, the specific precautions should be directly stated in the SOP.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(13)

Comments: _____

POTSOP400
Does the SOP Manual include criteria for the frequency and number of control and calibration materials?

Yes ☐ No ☐ N/A ☐

POTSOP400
The potency SOP and any associated extraction SOPs must outline the number of controls and calibrators required for the method, as well as control and calibration frequency. At a minimum, controls and calibration should be completed at the frequency outlined in the quality assurance and quality control section of this document (POTQCM).

Evidence of Compliance:
- SOPs clearly articulate the required method controls and the frequency of analysis.
- SOPs clearly articulate the required calibrators and the frequency of analysis.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(14)

Comments: _____

POTSOP500
Does the SOP Manual include criteria for recording and reporting assay results?

Yes ☐ No ☐ N/A ☐

POTSOP500
The laboratory reports for potency testing should include all information described in GENREP300 in the CDPHE General Audit Checklist and in the Reporting section of this document. The SOP should outline, in detail, the recording of results and reporting results to clients, as well as the entry of results into the METRC data system.

All test results must be reported in METRC as part of daily reconciliation by the close of business.

REFERENCES: DOR 1 CCR 212-3 5/6-425(15)

Comments: _____

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POTSOP600
Does the SOP Manual include pertinent literature references for each method?

Yes ☐ No ☐ N/A ☐

POTSOP600
Literature references must be peer-reviewed if not published by a government agency. For a nonexclusive list of appropriate references, see the CDPHE Marijuana Testing Reference Library.

Applicable references may include, but are not limited to:

- Backer, Benjamin De., et al., 2009. Innovative development and validation of an HPLC/DAD method for the qualitative and quantitative determination of major cannabinoids in cannabis plant material. Journal of Chromatography B, 887 4115/6-4124
- Bovens, Michael., et al., 2009. Recommended method for the identification and analysis of cannabis and cannabis products: manual for use by National drug analysis laboratories. United Nations.

REFERENCES: DOR 1 CCR 212-3 5/6-425(17)

Comments: _____

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POTSOP700
Do laboratory SOPs include step-by-step instructions with sufficient detail to perform the assay, to include equipment operation and any abbreviated versions used by a testing analyst?

Yes ☐ No ☐ N/A ☐

POTSOP700
SOPs must contain detailed descriptions of how to perform a task, so an employee may perform the task in the same manner every time.

Evidence of Compliance:
SOPs include:

- Materials/equipment list and equipment parameters.
- Any pre/post-analytical cleaning.
- Instructions for making/procuring/utilizing method materials.
- Procedural operations, such as Test Batch/laboratory sample preparation and analysis.
- Applicable calculations.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(18)

Comments: _____

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POTSOP800
Does the SOP Manual include acceptability criteria for the results of controls?

Yes ☐ No ☐ N/A ☐

POTSOP800
Acceptability criteria for all calibration and QC materials (e.g., controls, spikes, blanks, etc.) must be defined, as well as the action to be taken when results are outside satisfactory control limits. When possible, acceptability criteria should be determined using testing data to establish statistically valid control ranges for each procedure. Acceptability criteria must not be too loosely defined or set in a manner that could jeopardize the integrity of the result.

Evidence of compliance:

- Clearly defined acceptance criteria, quality control tracking procedures, and protocols for corrective actions.

REFERENCES: DOR 1 CCR 212-3 6-425(A)(19)

Comments: _____

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POTSOP900
Does the laboratory SOP manual include acceptability criteria for variances between different aliquots and different columns?

Yes ☐ No ☐ N/A ☐

POTSOP900
The laboratory must define acceptability criteria for the allowable variance between aliquots, duplicates, and new standard lots and when major maintenance/changes occur, such as replacing a column or switching column types.
Repeatability and precision assessment should be calculated and reported as relative percent difference between two aliquots (e.g., duplicate samples).

REFERENCES: CLINICAL LABORATORY IMPROVENT AMENDMENTS (CLIA) §493.51; DOR 1 CCR 212-3 5/6-425(A)(19)

Comments: _____

POTSOP1000
Does the SOP Manual include a documented system for reviewing the results of controls, standards, and test results?

Yes ☐ No ☐ N/A ☐

POTSOP1000
The SOP manual must describe a procedure for the review of all analytical data. See GENSOP1300 in the CDPHE General Audit Checklist for additional guidance.

Evidence of compliance:

- Documented review of the analysts maintaining/setting up/performing lot checks of standards and controls (bench sheets, employee competency, training records, etc.).
- Documented review of Test Batch/laboratory sample preparation records.
- Documented primary and secondary review (all analytical data must be reviewed by two separate reviewers for errors and remediated prior to accepting/rejecting results).

REFERENCES: GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL EPA/600/B-07/001
DOR 1 CCR 212-3 5/6-425(A)(20)

Comments: _____

POTSOP1100
Does the SOP Manual include a documented system of reviewing for clerical errors, analytical errors, and any unusual analytical results?

POTSOP1100
The SOP Manual must describe a procedure for review of routine/daily testing, including how review is to be documented. Review must be documented to reflect that each analytical result reported has been evaluated as required by the SOP.

Evidence of compliance (including, but not limited to):

- Documented review of results (ensure that test results are reported in the proper units, for the proper Test Batches, and that laboratory samples and control results meet all of the aforementioned checks and balances.)
- Documented review of transcribed data to prevent errors in data entry (this may include results, client information, etc.).
- Documented review of unusual analytical results (co-eluting peaks, peak tailing or fronting, baseline wander and drift, etc.)
- Documented review of analytical errors (incorrect calculations, dilution factors, etc.)

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(20)
GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL EPA/600/B-07/001

Comments: _____

Validations:

In order to have confidence in laboratory methodology, certain criteria must be established, met and shown to be consistent. The application of parameters applied during method validation, allow for the general acceptance of data generated during analysis.

COLORADO
Department of Public Health & Environment

POTVAL100
Has the laboratory validated the method following good laboratory practices prior to reporting results?

POVAL100
Validations of new methodologies/platforms must include, when applicable, but are not limited to:

- Accuracy
- Precision
- Analytical sensitivity
- Analytical specificity
- Limit of Detection (LOD)
- Limit of Quantification (LOQ)
- Linearity/Reportable range
- Recovery
- Repeatability
- Identification of interfering substances

The fundamental parameters for proper validation include those listed. Validation involves documenting the performance characteristics of the method, showing that performance is suitable for the intended application. Method validation documentation must be maintained by the laboratory, which includes, but is not limited to, the raw analytical data and a validation report containing sufficient information that the study could be repeated.

Software must be validated prior to testing Test Batches, including but not limited to:

- analytical software.
- application programming interface(s) (APIs).
- laboratory information management systems (LIMS), etc.

Minimum compliance:

- To demonstrate accuracy, the laboratory must include at least five independent analyses per concentration level.
- Replicate analysis should include data from a minimum of two days where the number of replicates and test portions is at least greater than ten.
- The laboratory must establish the method LOQ (MLOQ) defined as the lowest value that can be quantified with at least 95% confidence.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-430(I)

Comments: _____

POTVAL200
Has the laboratory documented the validation of all methods including new methodology?

Yes ☐ No ☐ N/A ☐

POTVAL200
The laboratory should present validation data in a well formatted document, styled after peer-reviewed scientific publications, that includes sufficient information so that an experienced analyst could repeat the validation study. A validation report must accompany the raw data and should include, but need not be limited to:

- validation plan.
- introduction and brief summary.
- materials and preparation methods.
- method parameters.
- chromatograms, calculations and results.
- method acceptance limit performance data.
- instrument calibration data, if any.
- conclusion and discussion.
- references.

REFERENCES: DOR 1 CCR 212-3 5/6-430(I)

Comments: _____

POTVAL300
Has the laboratory validated or revalidated any new or revised methodology approved for use by the Laboratory Director prior to testing Test Batches?

Yes ☐ No ☐ N/A ☐

POTVAL300
Any changes to an approved methodology must be revalidated as appropriate. If the laboratory makes significant changes to the approved method, the method must be revalidated and provided to CDPHE.
A method validation or revalidation is required for the following:

- Submission of a new or original method.
- Expansion of the scope of an existing validated method.
- Modification of the range of the method beyond validated levels.
- Modifications which alter the method's performance specifications such as fundamental technology, reagents, instrumental parameters, or Test Batch/laboratory samples preparation, treatment, or extraction.

REFERENCES: DOR 1 CCR 212-3 5/6-430(I)(2)(3)

Comments: _____

POTVAL400
Has the laboratory, at a minimum, validated all state mandated matrices in accordance with 1 CCR 212-3 4-115(E); 5/6-430 (J)?

Yes ☐ No ☐ N/A ☐

POTVAL400
The laboratory must validate the following matrices:

- Flower
- Concentrates
- Infused Edible products
    - Chocolate, hard candy, brownie, etc.
- Infused Non-Edible products
    - Lotion, transdermal patches, etc.

Testing and Validation of Complex Matrices. A MTF must include a variety of matrices as part of the validation/verification process. During method validation/verification, a MTF must:

- Select matrices which best represent each category of products to be tested as listed in Rule 4-115(D). The laboratory shall independently determine the category of matrix a product falls within; properties to consider include fat content, cannabinoid content, pH, salt content, sugar content, water activity, the presence of know chemical compounds, microbial flora and antimicrobial compounds.

REFERENCES: DOR 1 CCR 212-3 4-115(D)(1);4-135(C)(5);5/6-430(I)(1) ;5/6-430(J)(1)

Comments: _____

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POTVAL500
Has the laboratory performed a new matrix validation, prior to reporting results, on matrices which are either a new category of matrix or are considerably different from the original matrix validated within the category?

Yes ☐ No ☐ N/A ☐

POTVAL500
The laboratory must fully ensure method fitness for any newly encountered matrix which was not included in the initial validation. For example, the MTF intends to receive the topical product “bath bombs” for testing, but previous validation studies for topical product included lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.

REFERENCES: DOR 1 CCR 212-3 5/6-430(J)(2)

Comments: _____

POTVAL600
Has the laboratory performed a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated but which fall within a category already validated?

Yes ☐ No ☐ N/A ☐

POTVAL600
The laboratory must ensure method fitness for any matrix encountered which, while included in the initial validation, differs in some way. For example, the MTF laboratory receives a new edible type matrix for testing (snickerdoodle cookies) but previous validation included gummies and hard candy. A spike of a portion of the submitted material must be analyzed prior to, or at the time of, laboratory sample analysis.

REFERENCES: DOR 1 CCR 212-3 5/6-430(J)(3)

Comments: _____

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POTVAL700
Has the laboratory established a written SOP for new or revised methodologies that is approved, signed, and dated by the Laboratory Director prior to use?

Yes ☐ No ☐ N/A ☐

POTVAL700
The Laboratory Director must approve, sign, and date all SOPs. All updated SOPs or re-validated methods must be approved and signed by the current Laboratory Director prior to use.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(7)

Comments: _____

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POTVAL800
Has the laboratory, at a minimum, validated for an appropriate range of concentration levels of all cannabinoids listed in 1 CCR 212-3 4-125(A)(2)?

POTVAL800
Laboratory methodologies must demonstrate, through validation, the capability of detecting an applicable range in concentrations of the eight stated cannabinoids: D8-THC, D9-THC, D10-THC, Exo-THC, THCA, CBD, CBDA and CBN.

D10-THC testing must include (6aR,9R)-delta10-THC and (6aR,9S)-delta10-THC.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 4-125(A)(2); 3-335 (K)

Comments: _____

POTVAL900
Has the laboratory, when required, performed a proper verification of a previously validated method?

POTVAL900
The laboratory shall perform a method verification for validated methods when there is change in testing location or the method is being adopted on a new instrument/platform.

Verification must include, when applicable, but is not limited to:

- Accuracy
- Precision
- Limit of Detection (LOD)
- Limit of Quantification (LOQ)
- Specificity (Only if different instrument sensitivity affects specificity)

The laboratory must verify method accuracy across the concentration range (if applicable, where concentration is greater than one order of magnitude) for which the laboratory intends to test, i.e., low, medium and high concentrations. Laboratories must demonstrate precision by performing a repeatability test at least once covering the range of concentrations for which the method is designed (if applicable, where concentration is greater than one order of magnitude).

LOD and LOQ must be verified through analysis of sample spikes at or close to the stated method LOD and LOQ.

In cases in which laboratory instrumentation differs from the instrumentation listed in the published standard method, the laboratory must verify specificity in matrix.

Yes ☐ No ☐ N/A ☐

REFERENCES: AOAC/ALACC 2007 Guide “How to Meet ISO 17025 Requirements for Method Verification”

Comments: _____

Analytical Processes:

High Performance Liquid Chromatography (HPLC) & Liquid Chromatography Mass Spectroscopy (LC-MS)

The analytical process can be described as consisting of four principle stages of operation:

1. Sampling
2. Isolation/separation of the desired constituent
3. Measurement/detection of the desired constituent
4. Calculation and interpretation of the data

P. J. Elving, *Anal. Chem.*, **1950**, *22* (8), pp 962–965 **DOI:** 10.1021/ac60044a002
Publication Date: August 1950

COLORADO
Department of Public Health & Environment

POTHPC100
Does the laboratory perform and document instrument preventative maintenance and repair as required by the manufacturer or SOP?

Yes ☐ No ☐ N/A ☐

POTHPC100
Routine preventative maintenance works to ensure that an instrument is kept in good condition and may assist in identifying potential problems. Maintenance operations are performed periodically to lessen the likelihood of instrument failure. If routine and preventative maintenance are not prescribed by the instrument manufacturer, the laboratory must establish its own maintenance requirements and schedule.

Evidence of compliance:

- Documentation of maintenance activities and instrument performance after maintenance.

REFERENCES: DOR 1 CCR 212-3 5/6-430(E)(1)

Comments: _____

POTHPC200
Does the laboratory evaluate the performance of the instrument when changes in detector, conditions, eluent, or column are made prior to reporting test results?

Yes ☐ No ☐ N/A ☐

POTHPC200
The laboratory shall evaluate the performance of the instrument after routine and preventative maintenance, as well as after major changes such as column replacement, eluent replacement, pump maintenance, etc. Should quality data show deviation from the defined acceptance criteria, the laboratory must issue corrective actions to evaluate the problem and come to a resolution prior to reporting results.

REFERENCES EPA – MANUAL FOR CERTIFICATION OF LABORATORIES ANALYZING DRINKING WATER
DOR 1 CCR 212-3 5/6-430(E)(4)

Comments: _____

POTHPC300
Does the laboratory monitor and document the performance of the HPLC instrument each day of testing?

Yes ☐ No ☐ N/A ☐

POTHPC300
The laboratory must establish and implement measures of and acceptability criteria for system suitability. This may include, but need not be limited to:

- Verification of system pressure
- Verification of passing quality controls (retention time match, accurate quantitation of each analyte, etc.)

The laboratory must ensure the HPLC instrument performs properly each day of testing. Should quality data show deviation from set acceptability criteria, the laboratory must issue corrective actions to evaluate the problem and come to a resolution prior to reporting results.

REFERENCES: DOR 1 CCR 212-3 5/6-430(E)(3); 5/6-440(A)(1)(B(16)

Comments: _____

POTHPC400
Has the laboratory created written standards for acceptability when eluting solvents are recycled?

Yes ☐ No ☐ N/A ☐

POTHPC400
Laboratories that elect to recycle solvents utilizing a rotary-evaporator or similar, must have a written SOP that outlines the recycling and solvent evaluation methods and includes acceptance criteria for any recycled solvents. Recycled solvents must be held to the same standards as purchased standards in terms of quality

REFERENCES: DOR 1 CCR 212-3 5/6-430(E)(5)

Comments: _____

POTHPC500
Does the laboratory document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system?

Yes ☐ No ☐ N/A ☐

POTHPC500
Monitoring of internal standard response is an important component of analytical run review. Any individual irregularities or gradual trends in internal standard response can indicate discrepancies in actual injection volume between injections, variability in instrument performance, or analyte response due to matrix affects. Documented monitoring can aid in identification of these issues and guide subsequent investigation and corrective actions.

REFERENCES: DOR 1 CCR 212-3 5/6-430(E)(7)

Comments: _____

POTLCM100
Does the laboratory perform and document routine and preventative maintenance as required by the manufacturer or SOP?

Yes ☐ No ☐ N/A ☐

POTLCM100
Routine preventative maintenance works to ensure that the instrument is kept in good condition and may assist in identifying potential problems. Maintenance operations are performed periodically to lessen the likelihood of instrument failure. If routine and preventative maintenance are not prescribed by the instrument manufacturer, the laboratory must establish its own maintenance requirements and schedule.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(1)

Comments: _____

POTLCM200
Does the laboratory evaluate the performance of the instrument when changes in source, conditions, detector, eluent, or column are made prior to reporting test results?

POTLCM200
The laboratory shall evaluate and document the performance of the instrument after routine and preventative maintenance, as well as after major changes such as column replacement, eluent replacement, pump maintenance, etc. Should quality data show deviation from the defined acceptance criteria, the laboratory must issue corrective actions to evaluate the problem and come to a resolution prior to reporting results.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(9)

Comments: _____

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POTLCM300
Does the laboratory monitor and document the performance of the LC/MS instrument each day of testing?

Yes ☐ No ☐ N/A ☐

POTLCM300
The laboratory must establish and implement acceptability criteria for system suitability. This may include, but need not be limited to:

- Verification of system pressure.
- Verification of acceptable tune parameters.
- Verification of passing quality controls (retention time match, accurate quantitation of each analyte, etc.).

The laboratory must ensure and document that the instrument performs properly each day of testing. Should quality data show deviation from set acceptability criteria, the laboratory must issue nonconformance with corrective actions to evaluate the problem and come to a resolution prior to reporting results.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)

Comments: _____

POTLCM400
Does the laboratory maintain records of mass spectrometric tuning?

Yes ☐ No ☐ N/A ☐

POTLCM400
The laboratory must keep records of mass spectrometric tuning and must perform tunes at a relevant frequency set by the laboratory. At a minimum, the laboratory should tune the mass spectrometer at the frequency specified by the manufacturer. Documentation must include the criteria whereby tuning procedures are deemed to be acceptable.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(3)

Comments: _____

POTLCM500
Does the laboratory document corrective actions if a mass-spectrometric tune is unacceptable?

Yes ☐ No ☐ N/A ☐

POTLCM500
The laboratory must establish and implement criteria to monitor the spectrometric tuning requirements. If a tune is unacceptable, a nonconformance initiated with corrective actions must be taken and documented to address and correct the failure(s).

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(4)

Comments: _____

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POTLCM600
Does the laboratory document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument?

Yes ☐ No ☐ N/A ☐

POTLCM600
The laboratory shall document and maintain records after major changes such as, but not limited to, column replacement, source change, instrument parameter adjustment, and eluent replacement.

REFERENCES: DOR 1 CCR 212-3 5/6-430(F)(8)

Comments: _____

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POTLCM700
Does the laboratory document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system?

Yes ☐ No ☐ N/A ☐

POTLCM700
Monitoring of internal standard response is an important component of analytical run review. Any individual irregularities or gradual trends in internal standard response can indicate discrepancies in actual injection volume between injections, variability in instrument performance, or analyte response due to matrix affects. Documented monitoring can aid in identification of these issues and guide subsequent investigation and corrective actions.

REFERENCES: NIH Guidelines on Good Clinical Laboratory Practice; DOR 1 CCR 212-3 5/6-430(F)(5)(6); EPA QA Handbook Vol II, Section 11.0

Comments: _____

POTCAL100
Does the laboratory perform and document a calibration curve with each analysis using at a minimum five calibrators throughout the reporting range?

Yes ☐ No ☐ N/A ☐

POTCAL100
The multipoint calibration should consist of one or more measurements of the analyzer responses to at least five different concentrations (preferably seven). It is prohibited to remove data points from within a calibration range while still retaining the extreme ends of the calibration range. If a calibration point fails, the laboratory should re-prepare and re-analyze the calibration standard.

REFERENCES: EPA METHOD 8000C DETERMINATIVE CHROMATOGRAPHIC SEPARATIONS

Comments: _____

POTCAL200
Are there records of the calibration on the instrument?

Yes ☐ No ☐ N/A ☐

POTCAL200
The laboratory must maintain records of instrument calibration. Previous calibration data should be properly labeled, stored and easily accessible to analysts.

REFERENCES: DOR 1 CCR 212-3 6-450(B)(7)

Comments: _____

POTCAL300
If the initial calibration is not performed on the day of analysis, is it possible to trace back directly to the initial calibration?

Yes ☐ No ☐ N/A ☐

POTCAL300
It is important the calibration data is traceable and recoverable. The calibration used for any individual analysis must be captured in the laboratory records.

REFERENCES: DOR 1 CCR 212-3 6-450(B)(7)

Comments: _____

POTCAL400
If an initial calibration is not performed on the day of analysis, is the calibration verified prior to the analysis of laboratory samples by an initial calibration verification?

Yes ☐ No ☐ N/A ☐

POTCAL400
Initial calibration verification (ICV) should be analyzed prior to laboratory sample analysis. The ICV must be generated from a source separate from the calibration and continuing calibration verification material. The laboratory must establish acceptance criteria as relevant to the method; typically, this is evaluated as percent recovery.
% Recovery = (measured value ÷ true value)*100).

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(17); PA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN

Comments: _____

POTCAL500
Are results quantitated from the most recent calibration, not the continuing calibration verification?

Yes ☐ No ☐ N/A ☐

POTCAL500
Calibration checks should only be used as verification of the initial calibration and should not be used to calculate results**.**

Continuing calibration verification (CCV) should be analyzed prior to sample analysis and every 10 – 20 samples thereafter (or after a 12-hour period, should less than 20 samples be analyzed). The CCV controls are generally created from the same source as the calibration material. The laboratory must outline acceptance criteria as relevant to the method; ideally, the CCV should fall within at least ± 15% of the spike value.

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN /001 *GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL* 212-3 5/6-430(F)(8)

Comments: _____

POTCAL600
If the results of laboratory samples are not bracketed by the initial calibration, are the results reported as having less certainty (defined qualifiers or flags, or an explanation in the case narrative)?

Yes ☐ No ☐ N/A ☐

POTCAL600
The laboratory must report measurements below or above the calibration range as estimated values, greater than/less than values, or non-numerical designations. The laboratory must report amounts below the limit of detection as less than values or as "trace." The reporting of values outside the quantified calibration range must be outlined in the appropriate SOP. For additional information, refer to the Reporting section of this checklist.

If dilution is required to obtain a quantifiable result within the calibration range, the dilution should be the lowest one required to bring the laboratory sample concentration within the initial calibration range. In addition, the method detection limit is elevated by the dilution factor, regardless of presence or absence.

REFERENCES: DOR 1 CCR 212-3 3-825 (B)(5); EPA 903 8-91 001 Chemical Concertation Data Near Detection Limit

Comments: _____

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POTCAL700
Does the laboratory document the calibration curve and verify that it has a correlation coefficient of 0.995 or greater?

Yes ☐ No ☐ N/A ☐

POTCAL700
The laboratory must ensure that calibration curves fall within laboratory established limits; established limits must require a correlation coefficient of 0.995 or greater.

REFERENCES: EPA SW-846 Method 8260

Comments: _____

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Quality Assurance & Quality Control:

Laboratory Quality Assurance Programs (QAP) encompass a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. Test results produced by MTFs have a significant influence on public health and industry product acceptability. A good QA system does *at least*:

- Establishes SOPs for each step of the laboratory testing process, ranging from specimen handling to instrument performance validation.
- Defines administrative requirements, such as mandatory recordkeeping, data evaluation, and internal audits to monitor adherence to SOPs.
- Specifies corrective actions, documentation, and the persons responsible for carrying out corrective actions when problems are identified; and
- Sustains high-quality employee performance.

(http://www.cdc.gov/labstandards/)

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POTQCM100
Does the laboratory, for qualitative analyses, analyze, at minimum, a negative and a positive control for each analyte analyzed with each batch of laboratory samples analyzed?

Yes ☐ No ☐ N/A ☐

POTQCM100
A qualitative positive control contains the analyte being tested; it reacts positively and demonstrates the test's ability to detect the expected analytes. A negative control does not contain the analyte being tested. It contains only the solvent or medium and demonstrates the test's ability to run without interference or contamination.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(9)

Comments: _____

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POTQCM200
Does the laboratory, for quantitative analyses, analyze, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve?

Yes ☐ No ☐ N/A ☐

POTQCM200
A quantitative positive control contains the analyte being tested at a known, theoretical concentration. The two levels of positive controls should challenge the low and high end of the corresponding calibration curve. Different concentrations of controls assure that a test run is valid and results are reliable throughout the whole range of the curve.

A negative or blank control should also be run to demonstrate the test's ability to run without interference or contamination.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(10)

Comments: _____

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POTQCM300
Does the laboratory use control material(s) that differ in source or, lot number, or concentration from the calibration material used with each analytical run?

Yes ☐ No ☐ N/A ☐

POTQCM300
A second source of control material, different from the calibration material, should be obtained. Second source calibration verification determines if the stock and working standards are accurate.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(11)

Comments: _____

POTQCM400
Does the laboratory, for multi-analyte assays, perform and document calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run?

Yes ☐ No ☐ N/A ☐

POTQCM400
The multipoint calibration should consist of analyzer responses to at least five different concentrations of the analyte of interest.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(12)

Comments: _____

POTQCM500
Does the laboratory analyze an appropriate instrument blank, reagent blank and matrix blank with each analytical run?

Yes ☐ No ☐ N/A ☐

POTQCM500
The laboratory must analyze an appropriate reagent blank and method/matrix blank with each analytical batch. The method blank control sample must consist of a matrix blank (flower, concentrate, edible, etc. or surrogate matrix that adequately demonstrates similar matrix effect and extraction recovery) and must be analyzed in the same manner as laboratory samples (carried through the complete preparation and analytical procedure.) Typically, an instrument blank follows a positive control in the analytical sequence to ensure the absence of target analyte carryover.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(13)

Comments: _____

POTQCM600
Does the laboratory analyze controls in the same manner as unknowns?

Yes ☐ No ☐ N/A ☐

POTQCM600
Method controls (positive and negative) must be analyzed in the same manner as client samples. To properly assess the entire testing process, controls must pass through every part of the method, including laboratory sample preparation, extraction, and analysis.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(14)

Comments: _____

POTQCM700
Are laboratory control samples (LCS-standard of known amount prepared from a source independent of calibration standards or a material containing a known amount of analyte) analyzed at a minimum of 1 per batch of 20 or less laboratory samples per matrix type per extraction or preparation method?

Yes ☐ No ☐ N/A ☐

POTQCM700
Laboratory control samples are used to demonstrate that the laboratory is in control of the processes involved in the preparation and analysis of specific tests. It is critical that the laboratory be able to not only accurately recover the target analytes, but also to be able to reproduce that action. A laboratory control sample duplicate (LCSD) can be used to demonstrate method repeatability.

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN (B)(11)

Comments: _____

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POTQCM800
Does the laboratory document the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the Standard Operating Procedure is met?

Yes ☐ No ☐ N/A ☐

POTQCM800
The laboratory must document the results of calibration standards and controls, and these results must be adequately reviewed to ensure acceptability prior to the reporting of results. All data review must be documented. Control charting shall be performed to facilitate identification of trends.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(15)

Comments: _____

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POTQCM900
Is a matrix spike duplicate (MSD) or a laboratory duplicate performed at a frequency of at least 1 in 20 samples, or less, per matrix, per sample extraction or preparation method?

POTQCM900
Analyses of matrix spike duplicates (MSD) or laboratory duplicates are used to evaluate analytical or measurement precision. Repeatability and precision assessment should be calculated and reported as Relative Percent Difference between aliquots of two (one duplicate per laboratory samples). Duplicate samples must be within ± 20% RPD. Relative Standard Deviation can be used to compare 3 or more replicates.

%RPD = ((|difference|)/average)*100
%RSD = (Standard deviation/mean)*100

Yes ☐ No ☐ N/A ☐

REFERENCES: EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN

Comments: _____

POTQCM1000
Does the laboratory document all troubleshooting and corrective actions taken when calibration, control, or standards do not meet acceptability criteria as defined in the Standard Operating Procedure?

Yes ☐ No ☐ N/A ☐

POTQCM1000
The laboratory should document all troubleshooting and corrective actions taken when calibration, control, or standards fail to meet acceptability criteria. This documentation should be detailed and include the type of problem, the cause of the problem, the steps taken to correct the problem, and where applicable, steps taken to amend customer results. The laboratory director or delegated supervisory analyst must consistently review, sign, and date all corrective actions to ensure appropriateness and effectiveness of corrective actions.

REFERENCES: DOR 1 CCR 212-3 5/6-440(B)(16) (B)(11)

Comments: _____

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POTQCM1100
Does the laboratory use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound of interest?

Yes ☐ No ☐ N/A ☐

POTQCM1100
Internal standard is used to monitor or improve the precision of analysis. An internal standard is a known concentration of a substance that is present in every laboratory sample analyzed. The purpose of the internal standard is to behave similarly (e.g., ionization potential and mass) to the analyte but to provide a signal that can be distinguished from that of the analyte. This minimizes errors caused by evaporation of solvents and injection errors or discrepancies. Surrogate Standards are analytes added to a laboratory sample at a known concentration in order to determine extraction efficiency; in addition, they are chemically similar to those analytes being extracted. Surrogate standards offer better data defensibility and, when used, satisfy the internal standard requirement.

REFERENCES: DOR 1 CCR 212-3 5/6-430(E)(6)(F)(5)

Comments: _____

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POTQCM1200
If manual integration of peaks is performed, are records maintained to recreate the manual integration?

Yes ☐ No ☐ N/A ☐

POTQCM1200
Generally, chromatographic peaks generated will be integrated using automated methods by the software provided by the instrument manufacturer. It may be necessary for an analyst to review the automated integration, make adjustments and manually integrate the peaks. The principles and the specific procedures for completing, documenting and reviewing manual integration must be applied consistently to ensure defensible integrations. Essential information associated with laboratory samples analysis including all information necessary for the reconstruction of the data must be maintained; this includes manual integration performed in accordance with the laboratory SOP.

REFENCES: www.nelac-institute.org/docs/meetings/newport2008/manual_integration_080115.pdf

Comments: _____

POTQCM1300
Do the records include the identification of any standards, internal standards, solvents, etc. used in the analysis and preparation of the Test Batches/laboratory samples?

Yes ☐ No ☐ N/A ☐

POTQCM1300
Tracking of standards, internal standards, solvents, reagents, etc. throughout the laboratory is an essential quality control practice. Proper traceability aids in materials accountability, defensibility of data and is a useful troubleshooting tool.

REFERENCES: DOR 1 CCR 212-3 5/6-425(A)(12)

Comments: _____

Reporting:

Proper laboratory reporting is essential to regulatory compliance and good client relations, as well as protecting public health. Results and interpretations must be conveyed in a way that customers can understand. Adequate reporting to MED is necessary to ensure that any public health hazards can be addressed and mitigated.

POTREP100
For flower and concentrate Test Batches, does the laboratory report potency results by listing a single percentage concentration for each Cannabinoid that represents an average of all sub-samples from within the Test Batch, including reporting of Total THC?

Yes ☐ No ☐ N/A ☐

POTREP100
The laboratory must ensure that an average cannabinoid concentration/percentage is obtained for all sub-samples comprising a Test Batch. This can be achieved by testing many increments from a submitted Test Batch or by properly homogenizing Test Batches prior to testing. The process by which the laboratory obtains an average result across all subsamples must be outlined in an appropriate SOP.

"Total THC" means the following:

- The sum of the percentage by weight of Delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877,
- Plus the percentage by weight of Delta-8-tetrahydrocannabinol (D8-THC),
- Plus the percentage by weight of Delta-9-tetrahydrocannabinol (D9-THC),
- Plus the percentage by weight of Exo-tetrahydrocannabinol (Exo-THC),
- Plus the percentage by weight of Delta-10-tetrahydrocannabinol (D10-THC). i.e. Total THC = (% D9-THCA * 0.877) + % D8-THC + % D9-THC + % Exo-THC + % D10-THC.

REFERENCES: DOR 1 CCR 212-3 1-115

Comments: _____

POTREP200
Does the laboratory report quantitative results that are only above the lowest concentration of calibrator or control standard used in the analytical run?

Yes ☐ No ☐ N/A ☐

POTREP200
The laboratory may only report quantitative results that are above the limit of quantification (LOQ) and below the upper limit of quantification (ULOQ) and this must be specified in the laboratory SOP manual. Results below the LOQ or above the ULOQ may be reported qualitatively as described by the laboratory.

REFERENCES: DOR 1 CCR 212-3 3-825(B)(1))

Comments: _____

POTREP300
Does the laboratory verify results that are below the lowest concentration of calibrator or standard and above the LOQ by using a blank and a standard that falls below the expected value of the analyte in the laboratory sample duplicate prior to reporting a quantitative result?

Yes ☐ No ☐ N/A ☐

POTREP300
If quantifying below the lowest concentration of calibration, the laboratory should verify by analyzing a blank and a standard (and duplicate) that falls below the expected concentration of the analyte. Results must meet the established acceptability criteria.

REFERENCES: DOR 1 CCR 212-3 3-825(B)(2)

Comments: _____

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POTREP400
Does the laboratory qualitatively report results below the lowest concentration of calibrator or standard and above the LOD as either trace or using a non-specific numerical designation?

Yes ☐ No ☐ N/A ☐

POTREP400
Results below the lowest concentration of calibrator and above the LOD must be reported as qualitative results (i.e., trace or non-specific numerical designations such as “less than the lowest calibrator”).

Results below the LOD must not be reported as “zero” as this is misleading. These results could be reported as “non-detect”, as “less than the limit of detection”, or as the measured value with the associated uncertainty.

REFERENCES: DOR 1 CCR 212-3 3-825(B)(3)

Comments: _____

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POTREP500
Does the laboratory determine homogeneity in accordance with rule requirements?

POTREP500
If the Cannabinoid content of Retail/Medical Marijuana Product is determined not to be homogeneous, then it shall be considered to have failed potency testing.

A Production Batch of Retail/Medical Marijuana Product shall be considered homogeneous if a minimum of a total of four servings from two packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each Cannabinoid listed on the label.

A Production Batch of Retail/Medical Marijuana Product shall be considered homogenous if a minimum of a total of four servings from four individual single serve packaged units of a Test Batch has a relative standard deviation of less than 10 percent for each

Cannabinoid listed on the label.

i. Each of the four servings must also test within plus or minus 15 percent of the target potency.
ii. Any Cannabinoid that makes up less than 10 percent of the total amount of Cannabinoids in the marijuana product is not subject to this requirement.

Yes ☐ No ☐ N/A ☐

REFERENCES: DOR 1 CCR 212-3 4-115(E)(3)(a);(4)(a);

Comments: _____

POTREP600
A. Does the laboratory differentiate between retail and medical marijuana and marijuana products by reporting potency results for individually packaged Edible products greater than 100 mg +/- 15% THC as failing for retail products or passing for medical products?

B. Does the laboratory report failed potency testing when a single serving in an individually packaged Edible Retail/Medical Marijuana Product contains more than 10 milligrams of THC?

Yes ☐ No ☐ N/A ☐

POTREP600
Medical and Retail

- If an individually packaged Edible Marijuana Product is determined to have more than the total milligrams of THC stated on the Container, or less than the total milligrams of THC stated on the Container, then the Test Batch shall be considered to have failed potency testing, except that the allowed 15% potency variance shall apply.
- For Regulated Marijuana Product with a target potency or label claim of any cannabinoid consisting of more than 2.5 milligrams per serving, the potency variance shall differ no more than plus or minus 15%.
- For Regulated Marijuana Product with a target potency or label claim of any cannabinoid consisting of 2.5 milligrams or less per serving, the potency variance shall differ no more than the greater of plus or minus 0.5 mg or 40 percent per serving.

Retail

- If an individually packaged Edible Marijuana Product is determined to have more than 100 milligrams of THC within it, then the Test Batch shall be considered to have failed potency testing.
- If a single serving in an individually packaged Edible Marijuana Product is determined to have more than 10 milligrams of THC, then the Test Batch shall be considered to have failed potency testing.

REFERENCES: DOR 1 CCR 212-3 4-115(E)(3)(b)(4)(b)(5)(a)(b)

Comments: _____

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References:

1. Agilent Troubleshooting guide "*LC and LC/MS Your Essential Resource for Columns & supplies*
2. AOAC Appendix K: Guidelines for Dietary Supplements and Botanicals
3. AOAC/ALACC 2007 Guide "*How to Meet ISO 17025 Requirements for Method Verification*"
4. CDPHE Marijuana Testing Reference Library
   https://cdphe.colorado.gov/laboratory-services/inspection-of-marijuana-testing-facilities/marijuana-reference-library
5. Colorado Code Regulations DOR 1 CCR § 212-3 October 2022
   https://www.colorado.gov/pacific/enforcement/med-rules
6. (CLIA) *CLINICAL LABORATORY IMPROVENT AMENDMENTS* §493.516.
7. EPA MODULE 1. GUIDANCE ON PREPARING A QA PROJECT PLAN
   https://www.epa.gov/sites/production/files/2015-06/documents/module1_0.pdf
8. EPA METHOD 8000C. "DETERMINATIVE CHROMATOGRAPHIC SEPARATIONS"
9. EPA QA Handbook Vol II, Section 11.0
   https://www3.epa.gov/ttnamti1/files/ambient/pm25/qa/vol2sec11.pdf
10. EPA/600/B-07/001 *GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES MANUAL*
    https://www.epa.gov/quality/guidance-preparing-standard-operating-procedures-epa-qag-6-march-2001
11. EPA 903 8-91 001 *Chemical Concentration Data Near Detection Limit*
    https://nepis.epa.gov/

12. EPA METHOD 8000D *DETERMINATIVE CHROMATOGRAPHIC SEPARATIONS*
https://www.epa.gov/sites/production/files/2015-12/documents/8000d.pdf

13. (CLIA) *CLINICAL LABORATORY IMPROVENT AMENDMENTS* §493.51

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15. The NELAC Institute - *Manual Integration* -
www.nelac-institute.org/docs/meetings/newport2008/manual_integration_080115.pdf

16. NIH *Guidelines on Good Clinical Laboratory Practice: Bridging Operations between Research and Clinical Research Laboratories*
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2213906/

17. Wisconsin Department of Natural Resources Section 08: Analytical Instrument Calibration
https://dnr.wisconsin.gov/topic/labCert/resources.html

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