Practical and Technical Issues Faced by Cannabis Laboratories

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Page Analytical

Outline

- Status of Lab Approval Requirements
- Analytical Categories Standards/Thresholds
- GxP

Whats Happening

- 23 State Managed Programs
  - 10 with Requirements for labs
    - ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
  - 2 drafting

Certification Need

- Confidence in Data and Product Safety
- Pathway for Enforcement and Evolution
- Trust

Trust Issues

- Potency
- Biological Contaminants
- Heavy Metals
- Pesticides
- Trace Solvents

Case #1

- A nationally recognized infused product manufacturer had made multiple batches of a product using a concentrate which had been tested prior to infusion. With product distribution, consumer feedback was that the product was ineffective. No post production quality testing had been performed. What happened?

Potency Analysis

- Sample Collection
  - USP <561>
    - Acidic vs NonAcidic Cannabinoids
    - GC vs LC
    - Overdose/Underdose

Case #1

- The infused product manufacturer was having his extract analyzed using GC and was told that it contained roughly 87% w/w THC. After the extract was reanalyzed using a liquid chromatographic method, it was discovered that the extract was in fact 49% w/w THC. The difference was due to the GC having decarboxylated the THC-A to THC. Due to the error that occurred during the initial analysis, the manufacturer added roughly half of the amount of extract needed to achieve the quantity listed on the package label resulting in a mishranded product and

Case #2

- An immunocompromised, kidney transplant recipient presenting with profound diarrhea, nausea and vomiting was admitted to hospital within 48 hours of smoking cannabis flower material. Is there a correlation?

Microbiology

Analysis	USP <1111>	USP <2023>	Colorado
Total Aerobic Count	<100 CFU/g	<10,000 CFU/g	N/A*
Total Combined Yeast and Mold	<10 CFU/g	<1000 CFU/g	N/A
Bile Tolerant Gram Negative	<1 CFU/g	<1000 CFU/g <100 CFU/g**	<10,000 CFU/g
E. coli	<1 CFU/g	<1 CFU/g	<1 CFU/g
Salmonella	<1 CFU/g	<1 CFU/g	<1 CFU/g

Microbiology

- 30-35% of samples fail to meet USP 2023 when adequate production controls are not in place
- Moisture Content
- With adoption of 2023 fewer complaints/returns

Case #2

- The patient had been given the flower material to conduct a “taste test” for review on the same day samples of that product were submitted to the laboratory for analysis. The samples analyzed tested positive for enterobacteria >100 cfu/g and combined yeast and mold >1000 cfu/g.
- Medical tests identified the patient as having contracted both respiratory aspergillus and gasterointestinal bacterial infections. As the product received by the patient had been completely consumed, no analysis

Aflatoxins

- Root/Rhizome
- Flower
- Concentrates

Do we need to test for Everything Always?

- Heavy Metals
  - COA
    - Annual Soil Testing
- Pesticides and Trace Solvents
  - Process Validation
- Randomized Analysis and COA Validation

Testing is Not Quality Control

- Good Manufacturing Practices
  - 21 CFR 111
  - Cost
  - Quality
  - Testing serves as Final verification

Questions