



PATIENT FOCUSED CERTIFICATION



a project of Americans for Safe Access Foundation

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Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Products

Docket No. FDA-2019-N-1482

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“The mission of Americans for Safe Access (ASA) is to ensure safe and legal access to cannabis (marijuana) for therapeutic use and research.”

Patient Focused Certification is a third-party independent compliance program developed to further the mission of Americans for Safe Access

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- Manufacturing and Product Quality
 - Industry standards
 - Cultivation, Manufacturing, Distribution, Testing
 - Representative sampling
 - Regulator training
- Validated analytical testing
 - Laboratory standards
 - Proficiency testing
- Product standards
 - Testing standardization
 - Contaminant limit standardization
- Safety Concerns
 - Pesticides
 - Residual solvents
 - THC content
 - Homogeneity



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Manufacturing and Product Quality

- Industry standards
 - Cultivation operations
 - Manufacturing operations
 - Distribution operations
 - Facilities
 - Personnel Education and Training
 - Packaging and labeling
 - Representative sampling
 - Regulator training



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Cannabis Inflorescence
Cannabis spp.

STANDARDS OF IDENTITY, ANALYSIS, AND
QUALITY CONTROL

Revision 2014





Validated Analytical Testing

- Testing harmonization and limits

- Potency
- Foreign matter
- Loss on drying
- Pesticides
- Microbial and fungi
- Heavy metals
- Residual solvents
- Sampling
- Proficiency testing

Pesticide Testing Requirements	California	Colorado	Oregon	Washington
Abamectin	0.3ppm	0.07ppm	0.5ppm	Screen
Imidacloprid	3ppm	0.02ppm	0.4ppm	Screen
Myclobutanil	9ppm	0.04ppm	0.2ppm	Screen
Permethrin (cis + trans)	20ppm	0.04ppm	0.2ppm	Screen
Spinosad	3ppm	0.06ppm	0.2ppm	Screen
Spiromesifen	12ppm	0.03ppm	0.2ppm	Screen



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Safety Concerns

- Pesticides
 - Recalls in states like Colorado, Oregon, and Washington for use of non-permitted pesticides or exceeding allowable limits
 - No Special Local Needs Registrations have been approved by EPA despite 4 states applying
- Residual solvents
 - Use of solvents varies by state
 - Recall in Colorado for ethanol exceeding allowable limit
 - Some locations permit hydrocarbons such as butane and propane
 - Equipment used in manufacturing



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Safety Concerns

- Potency of THC-rich products
 - Weight and rate of metabolism
 - Amount and type consumed
 - Method of consumption
 - Experience with cannabis
- Homogeneity
 - Distribution of cannabinoids in products that have multiple servings



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Thank you for your time!

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