STANDARDS AND INFORMATION FOR HEMP AND CBD

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Regulatory Manager

USP Dietary Supplement Stakeholders Forum
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What Differentiates Mile High?

1. Scale: Leading CBD extractor in the global market
2. Compliance: End-to-end GMP and ISO certified facility and processes

Extraction Process Highlights

1. Proprietary equipment
2. Continuous processing
3. Scalable technology
4. Low cost processor
**GMP Certified Facilities**

Our entire extraction and purification process from hemp to final product has been thoroughly inspected and audited by SGS, earning us GMP certification in 21 CFR Part 111 and 117.

**ISO 9001:2015 Certified**

Mile High Labs has completed an audit by SGS, the world’s leading inspection company, earning us our ISO 9001:2015 certification.

**Looking to the Future**

Mile High Labs is in the process of gaining certification for ISO 17025 for testing and calibration laboratories. Other certifications are planned for the immediate future.
Our Quality Management System (QMS) documents everything from receipt of hemp to product going out the door for full traceability and compliance to cGMP 111 & 117 as well as our ISO 9001:2015 certification.

What We Do:
- Supplier Quality
- Raw Material & Finished Product Testing
- Material Controls
- Master Batch Records for Each Product
## Ingredient Form Factors

<table>
<thead>
<tr>
<th>Spectrum</th>
<th>Consistency</th>
<th>Cannabinoid Content</th>
<th>Other Cannabinoids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated Cannabidiol</td>
<td>Broad Spectrum</td>
<td>&gt;98% CBD</td>
<td>0% other detectable cannabinoids or THC</td>
</tr>
<tr>
<td>THC-Free Distillate</td>
<td>Clear and Golden Viscous Oil</td>
<td>80-90% CBD</td>
<td>Other related cannabinoids</td>
</tr>
<tr>
<td>FlowForm Distillate</td>
<td>Non-Crystalizing Oil</td>
<td>45-60% CBD</td>
<td>CBG-rich (&gt;2.5%), other related cannabinoids</td>
</tr>
<tr>
<td>Cannabidiol Water Soluble</td>
<td>Highly Bioavailable Water-Based Liquid</td>
<td>20% CBD</td>
<td>0% other detectable cannabinoids or THC</td>
</tr>
<tr>
<td>Broad Spectrum Water Soluble</td>
<td>Highly Bioavailable Water-Based Liquid</td>
<td>10% CBD</td>
<td>Other related cannabinoids, less than 0.2% THC</td>
</tr>
<tr>
<td>Cannabigerol Isolate</td>
<td>Fluffy, Finely Crystallized Powder</td>
<td>&gt;98% CBG</td>
<td>0% other detectable cannabinoids or THC</td>
</tr>
</tbody>
</table>
Product Categories

- Pet & Animal Products
- Food & Beverage
- Health & Wellness
- Cosmetics & Beauty
- Nutraceuticals
Mile High Labs – Culture Built on Quality

At Mile High Labs, we share a collective vision for the longevity of the CBD and cannabinoid industry. With a culture built on quality, compliance, transparency and consistency, we are committed to operating the world’s most advanced extraction platform and making safe and effective cannabinoids accessible for all.

In the under-regulated world of CBD, we have taken a stand and made a commitment to act in a way that positively impacts consumers and the industry as a whole.
Industry Challenges

- Lack of oversight of the industry by regulatory bodies
- Global regulatory landscape varies and is constantly changing
- Industry has a bad reputation because of products on the market that do not match their label
Complexities of Hemp Extract

• Hemp starting material is variable and can result in extracts with inconsistent composition
• Extraction and purification methods vary and result in extracts with different cannabinoid profiles
• THC concentrates with processing
How USP Can Help Industry?

• Level the playing field by publishing standards for ingredients and products
• Standard methods and standard nomenclature for things like broad/full spectrum and isolate
• Clear hemp identification methods (beyond THC content)
• Set a limit (concentration or amount) of the THC allowed per unit
• LOD and LOQ established for sample types
• Work with other standards organizations to harmonize the standards
• Matrix specific methods for various product matrices
• Identify high risk pesticide residues for hemp
What Do We Expect from USP?

• Work with industry, other standards agencies and regulators (FDA) to come to a consensus on the standard

• Help to legitimize hemp products

• Act quickly to provide guidance to industry sooner rather than later

• Reference standards
MHL’s Experience in Industry with Standards

- Only as good as the lab or company using the standards
- Can take too long to publish the standards
- Too many standards make it confusing for industry
- Standards are focused on ingredients (hemp, distillate, isolate) and are often not appropriate for finished product analysis
Characterization of MHL Material

- Color and Appearance
- CBD content
- THC content (included THC and THCA)
- Other Cannabinoids
- Residual solvents
- Elemental impurities
- Pesticides
- Mycotoxins

Certificate of Analysis

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<tr>
<th>Test</th>
<th>Methodology</th>
<th>Specification</th>
<th>Test Results (Percentage)</th>
<th>Pass/Fail</th>
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<td>THC profile</td>
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</table>

Number of samples: 10

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Thank you to USP for inviting me to be a panelist member on this important topic of standards and information of hemp and CBD.

If you have any questions following today, please feel free to reach me at l.eder@milehighlabs.com
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