DEPARTMENT OF HEALTH

Hemp-Derived Cannabinoid Product Testing Guidance[1]

Introduction

Minnesota Statute 151.72 subd. 4 requires that manufacturers of hemp-derived cannabinoid products submit representative samples of each batch of a product to an independent, accredited laboratory for testing. Testing must be consistent with generally accepted industry standards for herbal and botanical substances, and, at a minimum, the testing must confirm that the product:

- contains the amount or percentage of cannabinoids that is stated on the label of the product
- does not contain more than trace amounts of any mold, residual solvents or other catalysts, pesticides, fertilizers, or heavy metals; and
- does not contain more than 0.3 percent of any tetrahydrocannabinol.

NOTE: A batch is a specific quantity of a specific product containing cannabinoids derived from hemp, including an edible cannabinoid product, that is manufactured at the same time and using the same methods, equipment, and ingredients that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled according to a single batch production record executed and documented.

This document provides information and guidance for ensuring that hemp derived cannabinoid products are tested to ensure they are safe for consumption. Testing should be conducted by a laboratory that operates formal management systems under the International Organization for Standardization. Testing should be completed on the final product that is offered for sale.

As research into hemp-derived cannabinoid use and safety advances, this document will be revised and updated to reflect the state of science as it pertains to the hemp-derived cannabinoid industry.

Testing of the hemp from which the hemp-derived cannabinoid product was derived, or possession of a certificate of analysis for such hemp, does not meet the testing requirements described above.

As required by MN Statute 151.72, upon the request of the Minnesota Department of Health (MDH), the manufacturer of the product must provide MDH with the results of the testing.

[1] NOTE: The information appearing in this document is for general informational purposes only and is not intended to provide legal advice to any individual or entity. We urge you to consult with your own legal advisor before taking any action based on information appearing on this document or any site to which it may be linked.

Testing

MDH recommends the following testing and maximum levels to meet the requirements of Minnesota Statute 151.72.

Analyte/Limit Testing Grid

Analyte	Maximum level	Comment	Guideline
METALS			
Arsenic	1.5 ppm	Consistently test for all listed metals.	Q3D Elemental Impurities Guidance for Industry*
Cadmium	0.5 ppm		
Lead	0.5 ppm		
Mercury	3.0 ppm		
TOXINS			
Aflatoxin B1	5 ppb	Consistently test for all four toxins. B1 has a limit of 5 ppb and there is a 20ppb total limit for all toxins combined.	American Herbal Pharmacopoeia Recommended Standards
Aflatoxin B2	- ppb		
Aflatoxin G1	- ppb		
Aflatoxin G2	- ppb		
Ochratoxin A	- ppb		
MICROBIALS			
Salmonella	Absence in 1g	Consistently test for all microbials.	American Herbal Pharmacopeia Cannabis Inflorescence*
E. coli	Absence in 1g		
Shiga Toxin producing E.coli (STEC)	Absence in 1g		
Salmonella, spp	Absence in 1g		
L. monocytogenes	Absence in 1g		
Mold and yeast	1,000 CFU/g		
Aerobic bacteria	100,000 CFU/g		
Bile tolerant gram negative bacteria	150 CFU/g		
PESTICIDES			
Specific to Pesticide		Consistent testing of product for pesticides shall occur once a manufacturer has notified the laboratory & MDH that they intend to use a particular pesticide which is required by MN Statute 151.7s subd. 4(b).	US Pharmacopeia Herbal Medicines Compendium Chapter 561**
SOLVENTS			
Pentane	3,000 ppm	When using Pentane as the solvent, Pentane testing will be required on all lots of final product formulation solution.	International Conference for Harmonisation (ICH) Guideline Q3C (R5) on

Analyte	Maximum level	Comment	Guideline
n-hexane	290 ppm	When using Hexane as the solvent, Hexane testing will be required on all lots of final product formulation solution.	Impurities: Guidelines for residual solvents*
Heptane	5,000 ppm	When using Heptane as the solvent, Heptane testing will be required on all lots of final product formulation solution.	
Benzene	2 ppm	When using Benzene as the solvent, Benzene testing will be required on all lots of final product formulation solution.	
Butane	5,000 ppm	When using Butane as the solvent, Butane testing will be required on all lots of final product formulation solution.	
Toluene	890 ppm	When using Toluene as the solvent, Toluene testing will be required on all lots of final product formulation solution.	
Total Xylenes	2,170 ppm	When using Xylenes as the solvent, Xylene testing will be required on all lots of final product formulation solution.	
Propane	5,000 ppm	When using Propane as the solvent, Propane testing will be required on all lots of final product formulation solution.	
Ethanol	5,000 ppm	When using ethanol as the solvent, ethanol testing will be required on all lots of final product formulation solution.	
POTENCY			
Total THC	+/-10%	Test for total THC per serving/package and total percent THC	

*Limits are at or below the recommended guidelines

**Specific tolerance limits are listed in table 4 of Chapter 561 of the U.S. Pharmacopeia Herbal Medicines Compendium

Minnesota Department of Health
Office of Medical Cannabis
PO Box 64975
St. Paul, MN 55164-0975
651-201-5598
health.cannabis@state.mn.us
www.health.state.mn.us

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To obtain this information in a different format, call: 651-201-5598.