Ohio Administrative Code

Rule 3796:4-2-04 Testing laboratory analysis requirements.

Effective: May 2, 2022

(A) A testing laboratory shall analyze a sample of at least one half of one percent of the net weight of the batch from each batch of dried, cured plant material intended to be sold to a dispensary licensed by the state of Ohio board of pharmacy for, at minimum:

(1) Moisture content;

(2) Water activity;

(3) Cannabinoid potency including, at minimum:

(a) Delta-8- tetrahydrocannabinol;-

(b) Delta-8- tetrahydrocannabinolic acid;;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as defined in 3796:1-1-01;

(h) Cannabinol (CBN); and

(i) any other cannabinoid determined by the Department.

(4) Foreign matter contamination;

(5) Microbial contamination;

(6) Mycotoxin contamination;

(7) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(8) Pesticide and fertilizer residue.

(B) A testing laboratory shall analyze a sample of at least one half of one percent of the net weight of the batch from each batch of plant material intended to be sold to a processor licensed by the department for use in the manufacture of medical marijuana products for, at minimum:

(1) Pesticide and fertilizer residue; and

(2) Cannabinoid potency for, at a minimum:

(a) Delta-8-tetrahydrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as defined in 3796:1-1-01;

(h) Cannabinol (CBN); and

(i) any other cannabinoid determined by the Department.

(C) A testing laboratory shall analyze a sample of one unit of the same size, weight, and volume intended to be packaged and sold to a licensed dispensary from each lot of medical marijuana products prior to sale to a dispensary licensed by the state of Ohio board of pharmacy for, at minimum:

(1) Cannabinoid potency including, at minimum:

(a) Delta-8-tetrahydrocannabinol;

(b) Delta-8-tetrahydrocannabinolic acid;

(c) Delta-9-tetrahydrocannabinol;;

(d) Delta-9-tetrahydrocannabinolic acid;

(e) Cannabidiol (CBD);

(f) Cannabidiolic acid (CBDA);

(g) THC Content as defined in 3796:1-1-01;

(h) Cannabinol (CBN); and

(i) any other cannabinoid determined by the Department.

(2) Foreign matter contamination;

(3) Microbial contamination;

(4) Mycotoxin contamination, if a medical marijuana extract was used in the manufacture of the

product that was not previously tested for mycotoxin contamination by a licensed testing laboratory;

(5) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for heavy metal contamination by a licensed testing laboratory;

(6) Pesticide and fertilizer residue, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for pesticide or fertilizer residue contamination by a licensed testing laboratory; and

(7) Residual solvents, if a hydrocarbon-based medical marijuana extract was used in the manufacture of the product that was not previously tested for residual solvent contamination by a licensed testing laboratory.

(D) A testing laboratory may perform analysis on marijuana-derived ingredients used in the manufacture of medical marijuana products, including but not limited to medical marijuana extract. When performing analysis on medical marijuana-derived ingredients, the following sample sizes and required tests shall apply:

(1) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a system utilizing hydrocarbon solvents for, at minimum:

(a) Pesticide and fertilizer residue; and

(b) Cannabinoid potency including, at minimum:

(i) Delta-8-tetrahydrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinolic acid;

(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as defined by 3796:1-1-01;

(viii) Cannabinol (CBN); and

(ix) any other cannabinoid determined by the Department.

(c) Mycotoxin contamination;

(d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(e) Residual solvents.

(2) A sample of at least one half of one percent of the net weight of the batch from a batch of medical marijuana extract derived from a system utilizing carbon dioxide for, at minimum:

(a) Pesticide and fertilizer residue; and

(b) Cannabinoid potency for, at a minimum:

(i) Delta-8-tetrahydrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinolic acid;

(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as defined in 3796:1-1-01;

(viii) Cannabinol (CBN); and

(ix) any other cannabinoid determined by the Department.

(c) Mycotoxin contamination; and

(d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury.

(3) A sample of at least one half of one per cent of the net weight of the batch from a batch of medical marijuana extract derived from a method that does not involve the use of a hydrocarbon or carbon dioxide as a solvent for, at a minimum:

(a) Cannabinoid potency including, at minimum:

(i) Delta-8-tetrahydrocannabinol;

(ii) Delta-8-tetrahydrocannabinolic acid;

(iii) Delta-9-tetrahydrocannabinol;

(iv) Delta-9-tetrahydrocannabinol;

(v) Cannabidiol (CBD);

(vi) Cannabidiolic acid (CBDA);

(vii) THC Content as defined by 3796:1-1-01;

(viii) Cannabinol (CBN); and

(ix) any other cannabinoid determined by the Department.

(b) Foreign matter contamination;

(c) Microbial contamination;

(d) Mycotoxin contamination;

(e) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(f) Pesticide and fertilizer residue.

(E) A testing laboratory may request additional sample material in excess of the amounts listed in this rule if necessary for completion of the required quality assurance tests.

(F) For the purposes of microbial contamination analysis, a sample provided to a testing laboratory shall be deemed to have passed if it satisfies the standards set forth in Table 9 of the "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control" (2014) monograph.

(1) If a batch of plant material is not deemed to have passed testing for microbial contamination, that batch may be designated for extraction by hydrocarbon-based or carbon dioxide-based methods

(2) Medical marijuana extract derived from a batch of plant material not deemed to have passed testing for microbial contamination must be tested for microbial contamination prior to use in the manufacture of medical marijuana products.

(G) For the purposes of mycotoxin contamination analysis, a sample provided to a testing laboratory pursuant to this rule shall be deemed to have passed if:

(1) The total of the detected amounts, if any, of aflatoxin B1, aflatoxin B2, aflatoxin G1, and aflatoxin G2 is less than twenty micrograms per kilogram; and

(2) The detected amount, if any, of ochratoxin A is less than twenty micrograms per kilogram.

(H) For the purposes of heavy metal contamination analysis, a sample provided to a testing laboratory shall be deemed to have passed if:

(1) The detected amount of arsenic, if any, is less than 0.14 micrograms per kilogram.

(2) The detected amount of cadmium, if any, is less than 0.09 micrograms per kilogram.

(3) The detected amount of lead, if any, is less than 0.29 micrograms per kilogram.

(4) The detected amount of mercury, if any, is less than 0.29 micrograms per kilogram.

(I) For the purposes of pesticide residue analysis, a sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for an approved pesticide chemical residue in a food item as set forth in Subpart C of 40 C.F.R. Part 180, as effective on September 8, 2017. A sample shall automatically be deemed to have failed if residue is detected from any pesticide not on the approved pesticide list maintained by the department, regardless of the detected level of residue.

(J) Except as provided in paragraph (G)(1) of this rule, if a sample is deemed to have failed tests for any contaminants listed in this rule, the cultivator or processor that provided the sample must immediately destroy the corresponding batch of plant material or extract or lot of medical marijuana products and document the destruction in the inventory tracking system.