

R68. Agriculture and Food, Plant Industry.

R68-29. Quality Assurance Testing on Cannabis.

R68-29-1. Authority and Purpose.

1) Pursuant to Subsection 4-41a-701(3), this rule establishes the standards for cannabis and cannabis product potency testing and sets limits for water activity, foreign matter, microbial life, pesticides, residual solvents, heavy metals, and mycotoxins.

R68-29-2. Definitions.

1) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including:

- a) pesticides;
- b) heavy metals;
- c) solvents;
- d) microbial life;
- e) toxins; or
- f) foreign matter.

2) "Analyte" means a substance or chemical component that is undergoing analysis.

3) "Batch" means a quantity of:

a) cannabis concentrate produced on a particular date and time, following clean up until the next clean up during which the same lots of cannabis are used;

b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis concentrate is used; or

c) cannabis flower from a single strain and growing cycle packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.

4) "Cannabinoid" means any:

a) naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1); or

b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.

5) "Cannabis" means any part of the marijuana plant.

6) "Cannabis concentrate" means the product of any chemical or physical process applied to cannabis biomass that concentrates or isolates the cannabinoids contained in the biomass.

7) "Cannabis cultivation facility" means a person that:

a) possesses cannabis;

b) grows or intends to grow cannabis; and

c) sells or intends to sell cannabis to a cannabis cultivation facility or a cannabis processing facility.

8) "Cannabis cultivation byproduct" means any portion of a cannabis plant that is not intended to be sold as a cannabis plant product.

9) "Cannabis derivative product" means a cannabis product made using cannabis concentrate.

10) "Cannabis plant product" means any portion of a cannabis plant intended to be sold by a medical cannabis pharmacy in a form that is recognizable as a portion of a cannabis plant.

11) "Cannabis processing facility" means a person that:

a) acquires or intends to acquire cannabis from a cannabis production establishment;

b) possesses cannabis with the intent to manufacture a cannabis product;

- c) manufactures or intends to manufacture a cannabis product from unprocessed cannabis or cannabis concentrate; and
- d) sells or intends to sell a cannabis product to a medical cannabis pharmacy.
- 12) "Cannabis product" means a product that:
 - a) is intended for human use; and
 - b) contains cannabis or delta 9-tetrahydrocannabinol.
- 13) "CBD" means cannabidiol (CAS 13956-29-1).
- 14) "CBDA" means cannabidiolic acid, (CAS 1244-58-2).
- 15) "Certificate of analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for that testing was performed.
- 16) "Department" means the Utah Department of Agriculture and Food.
- 17) "Final product" means a reasonably homogenous cannabis product in its final packaged form created using the same standard operating procedures and the same formulation.
- 18) "Foreign matter" means:
 - a) any matter that is present in a cannabis lot that is not a part of the cannabis plant; or
 - b) any matter that is present in a cannabis or cannabinoid product that is not listed as an ingredient.
- 19) "Industrial hemp" means a cannabis plant that contains less than 0.3% total THC by dry weight.
- 20) "Industrial hemp waste" means:
 - a) a cannabinoid extract derived from industrial hemp with greater than 0.3% THC by mass; or
 - b) industrial hemp biomass with a THC concentration of less than 0.3% by dry weight.
- 21) "Lot" means the quantity of:
 - a) flower from a single strain of cannabis and growing cycle produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or
 - b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.
- 22) "Pest" means:
 - a) any insect, rodent, nematode, fungus, weed; or
 - b) any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment or that the department declares to be a pest.
- 23) "Pesticide" means any:
 - a) substance or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest or that the commissioner declares to be a pest;
 - b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and
 - c) any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own used with a pesticide to aid in the application or effect of a pesticide.
- 24) "Sampling technician" means a person tasked with collecting a representative sample of a cannabis plant product, cannabis concentrate, or cannabis product from a cannabis production establishment who is:

- a) an employee of the department;
 - b) an employee of an independent cannabis laboratory that is licensed by the department to perform sampling; or
 - c) a person authorized by the department to perform sampling.
- 25) "Standard operating procedure" (SOP) means a document providing detailed instruction for the performance of a task.
- 26) "THC" means delta-9-tetrahydrocannabinol (CAS 1972-08-3).
- 27) "THCA" means delta-9-tetrahydrocannabinolic acid (CAS 23978-85-0).
- 28) "Total CBD" means the sum of the determined amounts of CBD and CBDA.
- 29) "Total THC" means the sum of the determined amounts of delta-9-THC and delta-9-THCA, according to the formula: Total THC = delta-9-THC + (delta-9-THCA x 0.877).
- 30) "Unit" means each individual portion of an individually packaged product.
- 31) "Water activity" is a dimensionless measure of the water present in a substance that is available to microorganisms; calculated as the partial vapor pressure of water in the substance divided by the standard state partial vapor pressure of pure water at the same temperature.

R68-29-3. Required Cannabis and Cannabis Product Tests.

- 1) Prior to the transfer of cannabis biomass from a cannabis cultivation facility to a cannabis processing facility, the cultivation facility must make a declaration to the department that the biomass to be transferred is either a cannabis plant product or a cannabis cultivation byproduct.
- 2) A cannabis cultivation facility may not transfer a cannabis plant product to a cannabis processing facility unless an independent cannabis testing laboratory has tested a representative sample of the cannabis to determine:
 - a) the water activity of the sample;
 - b) the amount of total delta9-THC and total CBD present in the sample; and
 - c) the presence of adulterants in the sample, as specified in table 1.
- 3) Cannabis cultivation byproduct shall either be:
 - a) chemically or physically processed to produce a cannabis concentrate for incorporation into cannabis derivative product; or
 - b) destroyed pursuant to Section 4-41a-405.
- 4) Prior to its incorporation into a cannabis derivative product, cannabis concentrate shall be tested by an independent cannabis testing laboratory to determine:
 - a) the amount of total THC and total CBD present in the sample; and
 - b) the presence of adulterants in the sample, as specified in table 1.
- 5) Prior to the transfer of a cannabis product to a medical cannabis pharmacy a representative sample of the product shall be tested by an independent cannabis testing laboratory to determine:
 - a) the water activity of the sample, as determined applicable by the department;
 - b) the quantity of any cannabinoid or terpene to be listed on the product label; and
 - c) the presence of adulterants in the sample, as specified in table 1.
- 6) Testing results for cannabis plant product and cannabis concentrate may be applied to cannabis product derived therefrom, provided that the processing steps used to produce the product are unlikely to change the results of the test, as determined by the department.
- 7) Mycotoxin testing of a cannabis plant product, cannabis concentrate, or cannabis product may be required if the department has reason to believe that mycotoxins may be present.

8) A cannabis plant product, cannabis concentrate, or cannabis product that fails any of the required adulterant testing standards may be remediated by a cannabis cultivation facility or cannabis processing facility after submitting and gaining approval for a remediation plan from the department.

9) A remediation plan shall be submitted to the department within 15 days of the receipt of a failed testing result.

10) A remediation plan shall be carried out and the cannabis plant product or cannabis concentrate shall be prepared for resampling within 60 days of department approval of the remediation plan.

11) Resampling or retesting of a cannabis lot or batch that fails any of the required testing standards is not allowed until the lot or batch has been remediated.

12) A cannabis lot or cannabis product batch that is not or cannot be remediated in the specified time period shall be destroyed pursuant to Section 4-41a-405.

13) In the event that tests results cannot be retained in the Inventory Control System, the laboratory shall:

- a) keep a record of all test results;
- b) issue a certificate of analysis for all required tests; and
- c) retain a copy of the certificate of analysis on the laboratory premises.

14) Industrial hemp waste purchased by a cannabis cultivation facility in the form of a plant product or a concentrate must meet department cannabis testing standards as determined by an independent cannabis testing laboratory prior to its transfer to a cannabis cultivation facility.

15) Industrial hemp waste that is transferred to a cannabis cultivation facility shall be considered to be cannabis for all testing and regulatory purposes of the department.

TABLE 1
Required Tests by Sample Type

Test	Cannabis Plant Product	Cannabis Concentrate	Cannabis Product
Moisture Content	Required	X	X
Water Activity	Required	X	X
Foreign Matter	Required	Required	Required
Potency	Required	Required	Required
Microbial	Required	Required	Required
Pesticides	Required	Required	Required
Residual Solvents	X	Required	Required
Heavy Metals	Required	Required	Required
Mycotoxins	X	Required	X

R68-29-4. Sampling Cannabis and Cannabis Products.

1) The entity that requests testing of a cannabis plant product lot or cannabis concentrate batch, or cannabis product batch shall make the entirety of the lot or batch available to the sampling technician.

2) The lot or batch being sampled shall be contained in a single location and physically separated from other lots or batches.

3) The sample shall be collected by a sampling technician who is unaffiliated with the entity that requested testing of the cannabis lot or cannabis product batch unless an exception is granted by the department.

4) The owner of the cannabis lot or cannabis product batch and any of their employees shall not assist in the selection of the sample.

5) The sampling technician shall collect the representative sample in a manner set forth in a SOP, that is ISO 17025 compliant, maintained by the laboratory that will perform the testing.

6) When collecting the representative sample, the sampling technician shall:

a) use sterile gloves, instruments, and a glass or plastic container to collect the sample;

b) place tamper proof tape on the container; and

c) appropriately label the sample pursuant to Section R68-30-6.

7) For cannabis plant product lots the minimum representative sample shall be taken according to the following schedule:

a) 10 subunits with an average weight of one gram each for lots weighing 5 kilograms or less;

b) 16 subunits with an average weight of one gram each for lots weighing 5.01-9 kilograms;

c) 22 subunits with an average weight of one gram each for lots weighing 9.01-14 kilograms;

d) 28 subunits with an average weight of one gram each for lots weighing 14.01-18 kilograms;

e) 32 subunits with an average weight of one gram each for lots weighing 18.01-23 kilograms.

8) For cannabis concentrate the minimum representative sample shall be taken according to the following schedule:

a) 10 mL for batches of one liter or less; or

b) 20 mL for batches of four liters or less.

9) For cannabis products in their final product form the following minimum number of sample units must be taken, the combined total weight of which must be at least 10 grams, not including packaging materials:

a) four units for a sample product batch with 5-500 products;

b) six units for a sample product batch with 501-1000 products;

c) eight units for a sample product batch with 1,001-5,000 products; and

d) ten units for a sample product batch with 5,001-10,000 products.

10) Additional material may be included in the representative sample if the material is necessary to perform the required testing.

R68-29-5. Moisture Content Testing and Water Activity Standards.

1) The moisture content of a sample and related lot of cannabis shall be reported on the COA as a mass over mass percentage.

2) A sample and related lot of cannabis fail quality assurance testing if the water activity of the representative sample is found to be greater than 0.65.

3) A sample and related cannabis or cannabinoid product batch intended for human consumption fail quality assurance testing if the water activity of the representative sample is greater than 0.65, unless water is a component of the product formulation and is listed as an ingredient.

R68-29-6. Foreign Matter Standards.

1) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing if:

- a) the sample contains foreign matter visible to the unaided human eye;
- b) the sample is found to contain microscopic foreign matter estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory; or
- c) foreign matter is found that is suspected to have been intentionally added to the sample to increase its visual appeal or market value.

R68-29-7. Potency Testing.

1) A lot or batch of cannabis plant product, cannabis concentrate, or cannabis product shall have their potency determined and listed on a COA as total delta-9-THC and total CBD.

R68-29-8. Microbial Standards.

1) A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for microbiological contaminants if the results exceed the limits as set forth in Table 2.

TABLE 2
Microbial Analytes and Action Levels

Material	Microbial Limit Requirement (cfu)
Flower	Total Aerobic Microbial Count $\leq 100,000$ Absence of E. Coli and Salmonella spp. Absence of Aspergillus
Concentrated oil	Total Aerobic Microbial Count $\leq 10,000$
Wax	Total Combined Yeast and Mold Count $\leq 1,000$
Resin	Absence of STEC Absence of Pseudomonas Absence of Staph
Tablet	Total Aerobic Microbial Count $\leq 10,000$
Capsule	Total Combined Yeast and Mold Count $\leq 1,000$
Liquid Suspension	Absence of E. Coli and Salmonella spp.
Gelatinous cube	Absence of Staph
Transdermal	Total Aerobic Microbial Count ≤ 100 Total Yeast and Mold ≤ 10 Absence of Pseudomonas Absence of Staph

R68-29-9. Pesticide Standards.

- 1) Only pesticides allowed by the department may be used in the cultivation of cannabis.
- 2) If an independent cannabis laboratory identifies a pesticide that is not allowed under Subsection R68-29-5(1) and is above the action levels provided in Subsection R68-29-5(3) that lot or batch from which the sample was taken has failed quality assurance testing.
- 3) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing for pesticides if the results exceed the limits as set forth in Table 3.

TABLE 3
Pesticide Analytes and Action Levels

Analyte	Chemical Abstract Service (CAS) Registry number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Fonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
hexythiazox	78587-05-0	1
imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4

Kresoxim-methyl	143390-89-0	0.4
Malathion	143390-89-0	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

4) Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

5) Pyrethrins should be measured as the cumulative residues of pyrethrin 1 (CAS 121-21-1), cinerin 1 (CAS 25402-06-6), and jasmolin 1 (CAS 4466-14-2).

6) Abamectin is a composite of the amounts of avermectin B1a and avermectin B1b.

R68-29-10. Residual Solvent Standards.

1) A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fails quality assurance testing for residual solvents if the results exceed the limits provided in Table 4 unless the solvent is:

- a) a component of the product formulation;
- b) listed as an ingredient; and
- c) generally considered to be safe for the intended form of use.

TABLE 4
List of Solvents and Action Levels

Solvent	Chemical Abstract Service (CAS)Registry number	Action level Φppm
1,2 Dimethoxyethane	110-71-4	100
1,4 Dioxane	123-9	380
1-Butanol	71-36-3	5000
1-Pentanol	71-41-0	5000
1-Propanol	71-23-8	5000
2-Butanol	78-92-2	5000
2-Butanone	78-93-3	5000
2-Ethoxyethanol	110-80-5	160
2-methylbutane	78-78-4	5000
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butane	106-97-8	5000
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
2,2-dimethylbutane	75-83-2	290
2,3-dimethylbutane	79-29-8	290
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
1,4-dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5000
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
n-Hexane	110-54-3	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Methylpropane	75-28-5	5000
2-Methylpentane	107-83-5	290
3-Methylpentane	96-14-0	290
N,N-dimethylacetamide	127-19-5	1090
N,N-dimethylformamide	68-12-2	880
Pentane	109-66-0	5000
Propane	74-98-6	5000
Pyridine	110-86-1	100
Sulfolane	126-33-0	160

Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes	1330-20-7	2170

- 2) Xylenes is a combination of the following:
- a) 1,2-dimethylbenzene;
 - b) 1,3-dimethylbenzene;
 - c) 1,4-dimethylbenzene; and
 - d) ethyl benzene.

R68-29-11. Heavy Metal Standards.

A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for heavy metals if the results exceed the limits provided in Table 5.

TABLE 5
Heavy Metals

Metals	Natural Health Products Acceptable limits in parts per million
Arsenic	<2
Cadmium	<0.82
Lead	<1.2
Mercury	<0.4

R68-29-12. Mycotoxin Standards.

A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for mycotoxin if the results exceed the limits provided in Table 6.

TABLE 6
Mycotoxin

Test	Specification
The total of Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, and Aflatoxin G2	<20 g/kg of substance
Ochratoxin A.	<20 g/kg of substance

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