



Stability Protocols-FAQs

Q: Will the testing be for every “batch” defined the same as CoA testing (10lbs)?

A: No, testing will need to be done on each harvest batch. If the harvest batch is 100lbs thus requiring 10 CoA tests for release only one stability protocol would need to be performed.

Q: If there are multiple cultivars of the same strain is stability testing required on each?

A: Each strain as defined by its entry into METRC as a unique strain shall undergo stability testing.

Q: Will testing be required for every harvest batch moving forward?

A: No, each strain (as defined by its entry into METRC as a unique strain) will need to go through the complete stability protocol once.

Q: What types of processed products are subject to this stability protocol?

A: Products that contain processed cannabis plant material including all concentrates, vaporizer cartridges, suppositories, inhalers, dermal patches, and all topically applied products. Capsules that only contain cannabis concentrate with no added non-cannabis ingredients as well as tinctures that contain 50% or greater ethyl alcohol or glycerin and no added non-cannabis ingredients are subject to this protocol as well.

Q: Will this protocol be used for edibles in the future:

A: No, there will be an additional stability protocol for edibles.

Q: Will stability need to be repeated if packaging changes?

A: No. While repeated stability testing should be triggered by a change in grow conditions, product storage or packaging, COMAR has no requirement to report these changes. This information would be dependent upon self-reporting by licensees.

Q: Will accelerated stability testing be an option?

A: This is certainly a potential in the future but will not be included as an option in the initial implementation.

Q: Who will collect/prepare the samples?

A: Samples shall be chosen, labeled and placed into tamper evident packaging (e.g. tubes/bags with tamper evident labeling etc. as used currently for retain samples) by the independent testing laboratory, ideally at the time of CoA sample collection.

Q: Where will samples be stored?

A: All samples to be used in stability testing should remain with the manufacturer stored in the same conditions as product destined for market.

Q: Should products be in final packaging?

A: All samples should represent final, marketable product and therefore should be in final retail packaging including bags or boxes. The goal is to collect data representative of product on dispensary shelves and should reflect such.

Q: How will sample tampering be prevented?

A: While this isn't anticipated to be a problem at this point, tamper evident packaging/tape should be used as is currently being done with retain samples.

Q: Can time zero/baseline results be generated from the data obtained for CoA testing?

A: Yes.

Q: How will data be reported?

A: Results will be reported in a "stability study" area in METRC. All required information will be nested into this section. Complete data including any relevant notes will be uploaded to the reporting email address.

Q: Can data be uploaded in spreadsheet format?

A: Yes, this is preferred.

Q: Is it necessary to continue stability time-point testing after the product in question is no longer available/sold out?

A: Yes. The goal is to generate data to help better understand the stability of cannabis and cannabis containing products. This data may provide valuable information to help create a streamlined and effective stability and product safety program.

Q: Do results need to be reported at each interval or only at the completely of all study time-points?

A: Results from each time-point should be reported to the MMCC within 30 days of the identified time-point. (ex. 6 month data for samples taken on January 1st should be generated and reported to the MMCC by August 1st.)

Q: Will additional testing analytes be added such as BPA or additional metals testing?

A: Not in the first round of the program however this will continue to evolve and should continue to be discussed at future workshops.

Q: Will water activity be measured?

A: Water activity data for time zero/baseline will be generated through standard CoA testing but will not be required at the remaining time-points.

Q: Will mycotoxins be included in the stability protocols?

A: Mycotoxins are not required in the first round of the program. Inclusion of additional testing should continue to be discussed at future workshops.

Q: Will "deli style" storage of flower be assessed in the stability studies?

A: This is understood to be a need but will not be a part of the first round of the stability program.

Q: Will fresh frozen product be assessed in the stability program?

A: As all fresh frozen flower currently is destined for use in processed products and not being sold directly to dispensaries (and thus patients) it will not be stability tested until in its final, marketable form.

Q: How much sample should be collected for each time-point?

A: Sufficient sample to perform the required testing should be determined by the laboratory and documented in the study records. Multiple “final salable format” products may be required to achieve the required volume of sample for each time-point.

Q: Is it acceptable for licensees to change the lab used for testing stability time-points mid-protocol?

A: Yes, however if the lab changes mid-study this shall be reported to the MMCC and at the discretion of the MMCC may trigger testing to be repeated from time-point zero dependent on potential changes in testing methodology.

Q: Currently if any testing is open from a “batch” in METRC labs cannot release product for sale. Should an individual batch with its own METRC tags be required?

A: Each stability time point will require a separate package tag to avoid products being held in pending status at the retail level.