



## Explanation of New PHB Certificate of Analysis (CoA)

**Revision Date: 11/5/18**

A few FAQ answers:

1. What is different about this new CoA format?
  - a. It is important to have a comprehensive CoA that includes all the analyses which may be performed on any of our products. The previous CoA format only showed cannabinoid content. The new and improved CoA format shows not only potency, but many other testing results which are indicative of product quality. We have one of the most comprehensive CoA's in the CBD market and are happy to share all testing results for EVERY batch with our consumers.
2. Why do some of the analyses say "S.L." on my CoA?
  - a. S.L. means "Skip Lot". For that analysis, it means that analysis was not scheduled for qualification testing or identified by our skip lot protocol for testing. You will ALWAYS see CBD potency and THC potency on the CoA, along with all physical characteristics. If you would like to see the breakdown of other cannabinoids present besides CBD and THC, please see page 2 of the CoA, which is the previous CoA format.
3. What does "third party tested" really mean?
  - a. Third party testing is a common term used to communicate that external laboratories are utilized to provide independent test results. This offers a level of assurance that testing results are not biased. Additionally, when third party laboratories are used, many companies can compare testing results to further develop testing methods for their products. For industries which are in their infancy, like the CBD industry, this is important to establish reliable testing methods, and also to verify product quality.

### **Definitions:**

*Certificate of Analysis (CoA):* A summary of testing issued by Pure Hemp Botanicals (PHB) to communicate the testing performed on each batch of PHB product.

*Product:* The name of the product.

*Batch Number:* A unique identification number assigned by PHB which gives complete forward and backward traceability for all product ingredients, processing, and packaging.



*Manufacturer Item Number:* A unique identification assigned to a product, for ease of internal tracking.

*Date of Manufacture:* The date the product was produced.

*SOP No.:* Standard Operating Procedure (SOP) Number (No.): An internal number with revision for internal tracking and assurances that the most recent version and correct form is used for individual products.

*Expiration Date:* The minimum date the product will meet the specified label claims.

*Product Characteristics:* The description of the analyte being tested.

*Test Method:* The method used in order to provide a qualitative or quantitative result.

*Specification:* The minimum amount of the product characteristic that the product will contain at the Expiration Date. The specification is set to 95% of label claim, exceeding typical United States Pharmacopeia (USP) standard for 90% of label claim at time of expiration. Our products are always formulated with an overage to ensure label claims are met at time of manufacture, and specifications are met at time of expiration. Active ingredient degradation is expected and accounted for in our product formulations.

*Result:* The analytical value obtained by the specified test method.

*Organoleptic:* An analysis which uses the senses (taste, touch, feel, appearance, etc)

*High Performance Liquid Chromatography (HPLC):* An instrument used to quantify amounts of cannabinoids in products. This is preferable to Gas Chromatography (GC) as temperatures in the GC injection port can exceed the burnoff temperature of cannabinoids, causing inaccurate results.

*Marijuana Enforcement Division (MED):* The Colorado agency which regulates marijuana products. Even though hemp is not marijuana, PHB ensures their products meet the strictest standards set forth for product safety, including microbial determinations

*Inductively Coupled Plasma Mass Spectrometry (ICP-MS):* An instrument used to quantify amounts of heavy metals in products.

*United States Pharmacopeia (USP):* An organization which sets strict standards for dietary supplements. This organization also provides approved and validated testing methods appropriate for dietary supplements.

*Cannabidiol (CBD):* A non-psychoactive cannabinoid believed to have many health and wellness benefits. PHB tests every lot of product for CBD content to ensure consistent product delivery to our astute consumers.



*Tetrahydrocannabinol (THC):* A psychoactive cannabinoid present in hemp material, but below 0.3% on a dry weight basis.

*Residual Solvents:* Organic volatile chemicals that can or are used in production of hemp concentrates. PHB uses 100% food grade ethanol to extract CBD from hemp plant material. Additional processing steps are used to further purify the CBD concentrate to either a distillate or isolate form, which is then formulated into final products. All products are categorized into product families, which are then qualified by 3<sup>rd</sup> party testing to ensure compliance to MED residual solvent limits. Currently, the MED classifies the following as residual solvents: Acetone, Butanes, Ethanol, Heptanes, Isopropyl Alcohol, Propane, Benzene, Toluene, Pentane, Hexane, and Total Xylenes (m, p, o-xylenes).

*Pesticides:* PHB uses organic practices to grow our hemp plant material. You can be assured that prohibited pesticides are never used in our grow operation. All products are categorized into product families, which are then qualified by 3<sup>rd</sup> party testing to ensure compliance to MED pesticide limits.

*Heavy Metals (Arsenic, Cadmium, Lead, and Mercury):* Heavy Metals should be a significant concern for anyone consuming a CBD product derived from hemp. Hemp is a cumulative plant, meaning it absorbs contaminants from the soil, air, and water in which it grows. Customers should always ask the country and or state of origin for CBD products derived from hemp. Hemp sourced from countries like China, or India have greater potential for elevated levels of heavy metals, in exceedance of California Proposition 65 limits. At PHB, our facility encompasses the entire production process, from soil and plant to finished products. We grow our hemp locally and process the hemp into CBD based final products in one streamlined facility. To give our customers a high assurance of exceptional product quality, all products are categorized into product families, which are then qualified by 3<sup>rd</sup> party testing to ensure compliance to California Proposition 65 heavy metal limits.

*California Proposition 65:* Officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986. It was enacted to protect California's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects, or other reproductive harm. California is required to maintain a "list of chemicals known to the state to cause cancer or reproductive toxicity". The law also requires businesses to inform California consumers through labeling of any contaminants present from the list.

*Microbiological Characteristics:* Paramount to product safety is absence of microbiological contaminants, which may cause food-borne illness in consumers. USP sets standards for microbiological limits in food and dietary supplement products, which PHB follows. PHB uses aseptic (clean) manufacturing practices to ensure no contamination or cross-contamination occurs during the manufacturing, formulation, and packaging processes. The highest tier of PHB's quality assurance program revolves around product safety.



*Product Qualification:* A quality assurance program which, through analytical testing ensures overall product quality. PHB has a thorough product qualification program, which occurs on an annual basis. First, products are categorized into product families. Beginning in January, products are identified for qualification testing. A minimum of 3 lots from each product family is tested for every characteristic listed on the PHB CoA. After 3 lots have been tested and passed, skip lot protocol is implemented.

*Skip Lot Protocol:* Once a product family has been qualified as described above, skip lot protocol is implemented. In this protocol, about every 10<sup>th</sup> batch from a product family produced is tested for analytes on a rotating basis to ensure ongoing product quality and compliance to our specifications.

*< LOQ:* This is an abbreviation for “less than (<) Limit of Quantitation (LOQ)”. Our QC laboratory has performed method validation to ensure all analytical values are accurately reported. For cannabinoids which have “< LOQ” on the Certificate of Analysis, it means that the cannabinoid was detected (meaning the cannabinoid is present). However, we cannot accurately determine the amount in the sample as the amount detected by the HPLC instrument is below what can be accurately reported by our HPLC. A reported value of “< LOQ” for THC and THC maximum on a Greenhouse Growing System Certificate of Analysis will ALWAYS be less than the 0.3% THC requirement to classify a product as industrial hemp. Simply stated, you can think of a THC/THC maximum result of “< LOQ” to be equivalent to “< 0.3%”.

*N.D.:* This is an abbreviation for “Not Detected”. Our QC laboratory has performed method validation to ensure all analytical values and accurately reported. For cannabinoids which have “<N.D.” on the Certificate of Analysis, it means that the cannabinoid was not detected by our instrumentation (HPLC). A reported value of “N.D.” for THC and THC maximum on a Greenhouse Growing System Certificate of Analysis will ALWAYS be less than the 0.3% THC requirement to classify a product as industrial hemp. Simply stated, you can think of a THC/THC maximum result of “N.D.” to be equivalent to “< 0.3%”.

***ADDITIONAL TECHNICAL QUESTIONS MAY BE DIRECTED TO:***

***EMILY BOYD, DIRECTOR OF QUALITY***

***[EBOYD@ADVANCEDEXTRACTIONLLC.COM](mailto:EBOYD@ADVANCEDEXTRACTIONLLC.COM)***