AMERICAN KRATOM ASSOCIATION

GOOD MANUFACTURING PRACTICES - AUDIT REPORT FORM
AKA GMP Standards Program

HC USE ONLY	
File Number	Date/Time of Receipt

To be completed by an Independent 3rd Party Auditor.

GENERAL INFORMATION

A. Submission Information

1a. Date(s) of audit 1b. Purpose of audit: New Audit ☐ Renewal Audit ☐	2a. Date of inspection

B. Company Information

3. Company Name			
4. Address, Number/Street/Suite			
5. City/Town	6. Province/State	7. Postal Code/Zip Code	8. Country
9. Telephone Number	10. Fax Number	11. Website	

C. Company Point of Contact

12a. Name, Title	12b. Telephone Number

D. Auditor Information

15. Name(s):	
17. Qualifications and experience (attach additional information if necessary):	

F. Additional Notes:

18.

AUDIT CHECKLIST: STANDARD OPERATING PROCEDURES

Personnel		
The following standards have been implemented to: (a) Establish and follow written procedures to prevent microbial contamination from sick or infected personnel and for hygienic practices at the facility (b) Establish and implement a personnel compliance training program (c) Maintain documentation of training	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

Manufacturing Facility and Equipment		
The following standards have been implemented to: (a) Establish and implement procedures to ensure facility is in a condition that protects against the contamination of ingredients, finished products, and contact surfaces (b) Clean and sanitize storage, production, processing, and packaging areas according to an established schedule. (c) Verify the effectiveness of cleaning and sanitation operations by conducting swabbing of contact surfaces according to an established schedule and sampling plan	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

Manufacturing Operations		
The following standards have been implemented to: (a) Establish and implement written procedures for the processes of (1) receiving material; (2) quarantine; (3) production/processing; (4) packaging; (5) storage and sale. Maintain records of following these procedures on a per-batch basis. Document the rationale for what constitutes a "batch" or "lot" of product. (b) Establish and implement a written randomized sampling plan to a degree that would ensure a very low probability of an undetected contaminant. (c) Establish and implement a written procedure for analysis of raw materials for: 1. microorganisms of public health concern; 2. heavy metals; 3. chemical contaminants; 4. synthetic drugs; and 5. shelf-life testing (d) Establish and implement a raw material receiving procedure to place incoming raw materials on an initial quarantine pending receipt of test results and confirmation that ingredient meets specifications. This procedure should include a rejection protocol for raw materials that do not meet specifications or whose analysis reveals the presence of microorganisms of public health concern, heavy metals, chemical contaminants, or synthetic drugs. (e) Establish and implement a written procedure for qualifying ingredient suppliers, including the procedures that trigger the disqualification of the supplier.	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

AUDIT CHECKLIST: RECORDKEEPING

General

The following standards have been implemented to: (a) All records should be kept for a minimum of 1 year past the shelf life date of the product, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records. (b) All records should be kept in a standardized manner so that they are readily accessible at the manufacturing facility for review by an independent third party auditor.	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

Master Manufacturing Records

The following standards have been implemented to: (a) Establish and follow a written Master Manufacturing Record for each unique formulation of kratom product that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch. (b) The Master Manufacturing Records must: - Identify specifications for the steps in the manufacturing process where control is necessary to ensure the quality of the kratom product, and that the kratom product is packaged and labeled as specified in the master manufacturing record; and - Establish controls and procedures to ensure that each batch of kratom product manufactured meets the specifications in the Master Manufacturing Record. (c) The Master Manufacturing Records must include: - Name, strength, concentration, weight or measure of each ingredient used in each product for each batch size; - A statement of the theoretical yield of a manufactured kratom product expected at each step of the manufacturing process where control is needed to ensure the quality of the product, and the expected yield when manufacturing is completed, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision is made; - A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label; - Written instructions, including: ii. Specifications for each step in the manufacturing process where control is necessary to ensure the quality of the kratom product and that the kratom product is packaged and labeled as specified in the master manufacturing record;	Yes ☐	No ☐

iii. Procedures for sampling and a cross-reference to procedures for tests or examinations; iv. Specific actions necessary to perform and verify steps in the manufacturing process where control is necessary to ensure the quality of the kratom product and that the kratom product is packaged and labeled as specified in the master manufacturing record.		
If no, provide a rationale (e.g. Not applicable because…)		

Batch Production Records

The following standards have been implemented to: (a) Establish and maintain batch production records each time you manufacture a batch of a kratom product. (b) Batch Production Records must: - Include complete information relating to the production and control of each batch; and - Accurately follow the appropriate Master Manufacturing Record, and each step in the Master Manufacturing Record must be followed for each batch of product. (c) The Batch Production Records must include: - The batch, lot, or control number of the finished batch of kratom product; - The identity of the equipment and processing lines used in producing the batch; - The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross- reference to such records, such as individual equipment logs, where this information is retained; - The unique identifier assigned to each component, packaging, and label used; - The identity and weight or measure of each component used; - A statement of the actual yield and a statement of the percentage of theoretical yield at each phase of processing; - The actual results obtained during any monitoring operation; - The results of any testing or examination performed during the batch production, or a cross-reference to such results; - Documentation that the finished product meets the specifications established for the product; - Documentation, at the time of performance, of the manufacture of the batch, including the date on which each step of the master manufacturing record was performed and the initials of the persons performing each step of the master	Yes ☐	No ☐

manufacturing record; the packaging and labeling operations; and review by quality control personnel.		
If no, provide a rationale (e.g. Not applicable because…)		

Traceability		
The following standards have been implemented to: (a) Maintain records of the full chain of custody and master records for all purchased and sold items with standard double verification (e.g. a packer sign-off and Quality Control manager sign-off) (b) Establish and implement a supply chain system that allows a vendor to determine which customers received a given batch and from whom that batch of material was initially supplied by.	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

AUDIT CHECKLIST: ADVERSE EVENT REPORTING SYSTEM AND RECALLS

Written Adverse Event Reporting System

The following standards have been implemented to: (a) Review all product complaints to determine whether the product complaint involves a possible failure to meet the specifications for the product, or any other requirement in these standards or 21 C.F.R Part 111 that, if not met, may result in a risk of illness or injury. (b) Investigate any product complaint that involves a possible failure of a product to meet any of its specifications, or any other requirement in these standards or 21 C.F.R Part 111 that, if not met, may result in a risk of illness or injury. (c) Monitor consumers who experience an adverse health event related to a kratom product. (d) Monitor potential contamination or adulteration of kratom products. (e) Monitor vendors selling counterfeit, contaminated, or adulterated kratom products. (f) Monitor manufacturers or distributors of kratom products using health claims.	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

Recalls

The following standards have been implemented to: (a) Establish and implement a written recall procedure and conduct mock recalls according to procedure.	Yes ☐	No ☐
If no, provide a rationale (e.g. Not applicable because…)		

AUDIT CHECKLIST: MARKETING PRACTICES

Labeling and Advertising

The following standards have been implemented to: (a) The labels, labeling, or advertising of any kratom product should not bear any disease claims (i.e., claims regarding the treatment, cure, prevention, or mitigation of disease) or unauthorized health claims. (b) The labels, labeling or advertising of any kratom product should not bear any structure/function claims. (c) The labels, labeling or advertising of any kratom product should not reference any research or clinical data. (d) Each finished product label must include a batch or lot number. (e) Each finished product should be labeled to disclose the mitragynine and 7-OH alkaloid content of the product. (f) Each finished product must advise consumers to consult a physician for dosing information relative to alkaloid values.	Yes ☐	No ☐

(g) No kratom products may be sold to individuals under the age of 18. (h) The label should bear a statement that pregnant women should not use kratom products during pregnancy. (i) All labels, labeling, or advertising should include the following statement: "This product is not intended to diagnose, treat, cure, or prevent any disease or condition."		
If no, provide a rationale (e.g. Not applicable because…)		

ATTESTATION

I hereby certify that all information contained in, or referenced by, this report is true, accurate and complete. No information is false or misleading; no omissions have knowingly been made that may affect its accuracy and completeness.

Name(s) of Auditor (Please print)	Signature(s) of Auditor	Date yyyy-mm-dd

ATTESTATION (if applicable)

I hereby confirm that the company/facility referenced in Section B of this report has implemented and is following the AKA GMP Standards as outlined in the document found at http://www.americankratom.org/images/file/GMP-Standards-for-Kratom-Products.pdf

Name of Authorized Signing Official (Please print)	Signature of Authorized Signing Official	Date yyyy-mm-dd