

Beehive Botanicals, Inc.
Hayward, WI.

***GOOD
MANUFACTURING
PRACTICES
2000***

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GMP Manual

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**Beehive Botanicals, Hayward, WI.
Emergency Phone List**

	Home	Cellular
<u>Linda Graham</u>	634-8474 (634-3879)	715-558-1865
<u>Michelle Graham</u>	634-0401	715-558-1866
<u>Sally Gagan</u>	634-8328	715-558-2102
<u>Dan Lessard</u>		715-520-3800
<u>BIOTERRORISM REGISTRATION NUMBER: 1570190544</u>		
<u>Updated 3/06</u>		

Hayward Fire Department
911

Hayward Police Department
911

Good Manufacturing Practices for Dietary Supplements

Purpose: Good Manufacturing Practices (GMP's) as defined by the Food and Drug Administration in 21 CFR part 110 are the minimum sanitary and processing requirement for food companies. This manual provides written practices and procedures for the manufacture, processing, testing, packaging, labeling, storing and shipping of Beehive products.

We believe that these Good Manufacturing Practices are in the best interest of our customers. These guidelines provide reasonable assurance of our product's safety, quality, purity and potency and that they accurately and truthfully reflect our label claims.

Document Revisions: All addition, revisions and deletions to this document must be approved by the Quality Assurance Team and authorized by the CEO.

Product Standards

Dietary Supplements

Good Manufacturing Practices:

All products and procedures shall meet published Good Manufacturing Standards (GMP's). Where available and applicable, the specific GMP's issued by the C.R.N., NNFA, or AHPA shall be rigorously met.

Ingredients/Nutrients:

Only those dietary substances, which have a substantive and validated use in human nutrition, shall be used.

Only safe suggested dosage levels would be used.

All dietary substances must have a certificate of analysis verifying ingredient identity and quality. Kosher is available upon request.

All herb & food concentrates shall be certified organically grown whenever available when required by customer.

Only those substances, which are foods, food concentrates or substances found naturally occurring in foods shall be used.

Stimulants are specifically prohibited from inclusion in any formula either as a prime ingredient or in a base.

Ingredients/Excipients:

All excipients shall be purified pre-approved food grade products with applicable, published monographs.

No artificial preservatives, coloring, flavoring, stabilizer or additives shall be used.

Potencies, Overages & Weights:

All products shall be manufactured to provide label-claimed potencies of all nutrients through product shelf life.

All products shall be manufactured to ensure that nutrient overages do not exceed safe levels.

All capsules shall meet the proposed U.S. P. Standards for weight variation of >90%-110%<.

QUALITY CONTROL

Quality control is required during all stages of production and packing. The prime responsibility for Quality Control is on the entire operation. The responsibility of the Quality Controller is to evaluate the product, to assign the disposition (i.e. pass or reject) and in the case of problems to recommend possible solutions on the basis of available evidence.

To ensure efficient operation, full quality control testing must be maintained in the following areas:

1. Receipt of incoming materials
2. Bulk processed product (after all processing but before packing)
3. Packed product

B. INCOMING MATERIALS

1. The most important area for strict control is the receipt and acceptance of materials, to ensure that all material accepted is within the limits of the agreed specifications.
2. Whenever possible, the responsibility should be placed upon the supplier to produce evidence that the material meets all the requirements of the specification.
3. On receipt, the material will be examined by Quality Control personnel for organoleptic tests and will be compared to customer supplied Certificate of Analysis and Specification Sheet.
4. The number of samples taken for QC examination depends upon the size of the consignment and the number of units (boxes or drums) making up the consignment. As a general rule the following number of samples should be taken:

Number of Units	Number of Samples
1-5	Every unit
5-10	3
10-50	5
50-100	8
100+	Square root of number of units e.g. 150 units=12 samples 300 units=18 samples

The size of the sample should be double the amount required for all tests and to allow for re-testing. Powder & granular materials should be sampled with a clean stainless steel scoop and kept in a clean plastic bag. The bag should be clearly marked with the following information:

- a) Type of material
- b) Supplier
- c) Date sampled
- d) Supplier's batch or lot number
- e) Reference number of container sampled

All containers must be adequately re-sealed after sampling. Samples awaiting testing must be stored in a cool dry environment and should be tested as soon as possible.

Quality Control (continued)

In house testing will be performed on incoming raw material as needed or as specified by QC.

- Yeast & Molds
- E. Coli
- Total Coliform
- Enterobacteriaceae

Test results will be recorded and records kept on file for one year after date of expiration.

Once the results of the analyses are recorded the consignment is either released for production or held in quarantine on the basis of the results. If the analyses do not meet the requirements of the specifications, the consignment should be re-sampled and re-tested. If it again fails to meet the requirements, a decision to use or reject the material must be taken on all the information available. In all cases of material not meeting the specification, the supplier should be notified immediately.

5. If material held in the warehouse nears expiration date, it will be re-sampled and tested before being passed for production.

D. BULK PROCESSED PRODUCT

1. The bulk product accepted for processing must be used on a first-in-first out (FIFO) system to prevent undue delays in storage. The lot number should be noted on all paperwork to ensure that identification can be made accurately and easily. It is essential that accurate records be kept of all material movements from production to shipping.
2. As a general principle it should be remembered that all products have a maximum shelf life in the market.

E. PACKED PRODUCT

1. Product leaving the packing line must be sampled at frequent intervals, the frequency being determined by the speed of the packing line. At least one sample must be inspected from every processing lot that passes through the filling machines.
2. The packed product requires inspection for pack integrity, weights, codes, etc. Samples should be removed from the lines at regular intervals for external physical checks. These checks would normally be:
 - a. Seal integrity-all seals
 - b. Product net weight-count
 - c. Date and lot numbers correct
 - d. Correct register of all printing
 - e. External damage-scuffing, wrinkling, etc.

Quality Control (continued)

F. PACKAGING MATERIALS

1. Experience has shown that the materials used in the packaging of capsules and tablets do not have any adverse interaction between product and container. The entire packaging range meets the requirements of the FDA. Product specification sheets have been supplied for these.
2. The company's liquid products are packaged in industry acceptable containers.
3. Quality control undertakes regular spot checks on packaging, especially the carton, to ensure that the quality is maintained. Checks are also made on the label stock to ensure correct labels are being used. Checks are specifically made to ensure compatibility with product formulas, quantities, and shelf life dates. Regular verification of legal requirements of labeling is maintained.
4. Use of all packing material is on a strict FIFO basis to ensure wastage is kept to a minimum.

STABILITY AND SHELF LIFE

1. The object of setting a shelf life date is to ensure the maintenance of a consistent product throughout the storage life i.e. the claims made on the label are met at the end of the shelf life and the physical, chemical and organoleptic characteristics of the product are maintained.
2. The chemical and physical changes, which can occur, include degradation of solids, oxidation of oils, interaction of components and alteration in texture and disintegration. The organoleptic alterations over time include flavor, color and texture.
3. Beehive Botanicals has used the exact same formulas in all products for 5-15 years. Microbiology testing has been done on retained samples of products nearing their expiration dates. Also, active ingredients have been tested on pollen, propolis and royal jelly capsules.

Overages

To meet label claims for our products the contents of our products are overaged. This overage is meant to ensure that 100% of the label claim is met on the last day of the shelf life or in reality no less than 90% of label claim, but not to mislead or to be harmful to the consumer by adding excessive overages to a product to produce a longer shelf life. Overages have been used to ensure commercially acceptable shelf life for the Beehive Botanicals brand.

THE DETERMINATION OF THE BEEHIVE BOTANICALS PRODUCTS EXPIRY DATES

As stability of a product is the responsibility of the formulator, the contract suppliers of our products were contacted and their responsible persons advised a shelf life from the time of manufacture. The recommended shelf life for Beehive Botanicals products (including own manufacture) is as follows:

PRODUCT	RECOMMENDED SHELF LIFE
Capsules	3 years
Tablets	3 years
Liquids/Tinctures	3 years
Cosmetic Products	3 years
Personal care/Chewing gum	3 years

DEFINITIONS

BATCH: A specific process which is intended to produce a product of uniform character and quality within specified limits and is produced according to a single manufacturing order during the same cycle of manufacture. Each “batch” is identified by a specific combination of letters and or numbers from which the complete history of the manufacture processing, packaging, holding, and distribution of any specific “batch” can be determined.

LOT NUMBER-BATCH NUMBER: The specific combination of letters and or numbers assigned to each batch from which the complete history of the manufacturing, processing, packaging, holding, and distribution of any finished product or component can be determined.

COMPONENT: Means any ingredient, material, or substance intended for use in the manufacture, processing, packaging, or labeling of a product.

DIETARY SUPPLEMENT: Means a finished product (i.e. tablet, capsule, liquid powder) that contains one or more dietary substances. Such a product shall be represented to possess nutritional value.

DIETARY SUBSTANCE: Means any component that is intended to supplement the diet and is not represented for use as conventional food.

OTHER INGREDIENT: (Substance) means any component other than a dietary substance.

IN PROCESS MATERIAL: Means organizational unit designed to be responsible for duties relating to quality control.

AMOUNT: Means the concentration of a substance (i.e. weight/weight, weight/volume, or unit as a volume or weight basis): and/or the potency of the product as indicated by appropriate procedures.

ACCEPTANCE CRITERIA: Means the product specifications and acceptance/rejection criteria such as acceptable/unacceptable quality level, with an associated sampling plan. These criteria are necessary for making a decision to accept or reject a lot or batch of wither component materials or finished products.

REPRESENTATIVE SAMPLE: Means a sample that consists of a number of units based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

RANDOM SAMPLE: A sample taken from each lot of raw material used in a batch or by a number of containers statistically determined (the square root of samples plus one).

SANITIZE: Means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other microorganisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.