BLISTERPACK PRO	GOOD DOCUMENTATION PRACTICES	SOP #	1016GDP
		Revision #	001
		Implementation Date	10/16/2019
Page #	1 of 3	Last Reviewed/Update Date	01/12/2021
SOP Author:	Surinder Gidha	Q.A. Approval Signature	
		Management Approval Signature:	

Standard Operating Procedure

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SECTION:

I. Purpose

1.1. This procedure describes the documentation practices required to properly complete documents and make corrections to documents at Blisterpack Pro.

II. Scope

2.1. This procedure applies to all personnel required to complete or correct official controlled documents.

III. Responsibilities

3.1. Production

3.2. Quality Unit

3.3. Material Handling

3.4. Maintenance

3.5. Packaging

3.6. Sanitation

IV. Procedure

4.1. All good documentation practices are determined and approved by the Quality Unit.

4.2. Recording data on controlled documents:

A. All entries must be legible.

B. Most entries must be written in blue ink.

i. The quality unit may use red ink to record in-process checks as well as when grading training records.

ii. Only use pens supplied by Blisterpack Pro. Personal pens are not allowed.

C. All entries must be made at the time work is done.

i. Making entries before the work is done is not a good documentation practice and is not allowed.

D. All entries must be recorded exactly. If reading an instrument, record the exact reading on that instrument. Record all times to the minute.

i. Blisterpack Pro uses military time. 9:30 AM is recorded as 09:30. 2:30 PM is recorded as 14:30.

E. Initialing, signing, and dating:

i. Signatures and initials indicate that the work and documentation are correct and done in accordance to applicable procedures.

ii. When more than one person is responsible for the completion of a task, each person must sign/initial.

iii. Do not sign/initial for the performance of a task completed by someone else.

iv. Date the entry at the time work is performed. If dating the entry on a later date than when the work was done, supply the current date and explain the delay.

F. Do not leave sections blank on a controlled document. Line through any unused areas, write "not applicable" or "N/A," and date and initial.

4.3. Correcting errors on controlled documents:

A. Draw a single line through the error so that it is still legible. Write the correction next to the error and date and initial the date the correction was made.

i. Never use whiteout or correction tape.

ii. Never write over data – for example, make a 5 into a 6.

B. When the reason for the correction is not obvious, such as when entering the wrong date or time, explain the reason for the correction in a notation.

i. When uncertain about the notation of a correction, speak with a manager/supervisor.

C. Examples:

i. For an illegible entry – line out the illegible entry, rewrite the entry legibly, initial and date.

ii. For incorrect data – line out the original entry, write the correct entry, initial and date. Provide notation explaining the reason for the correction.

iii. For missing, non-measurement areas – fill in the area and initial and date. Provide notation explaining the reason for the correction.

iv. For missing measurement areas – write "missed" in place of the missed entry and initial and date. Measurement data must never be entered later.

D. Errors found in record review must only be corrected by the original author or the author's supervisor/manager.

4.4. Verification Documentation

A. A verification is a double-check for a critical stage of a process.

B. Verification is used when one person performs a task, and a second person verifies that the task has been performed correctly.

C. Verification provides assurance that work has been completed without mistakes.

D. Examples of when verification is required include:

i. Weighing raw materials

ii. Adding components to a batch

iii. Blend times

iv. Material and batch release

v. Finalizing test results

vi. Creating certificates of analysis

vii. Any other time documents call for verification.

E. A verification signature carries the same weight as any other signature. The person performing the verification bears the ultimate responsibility of defending the accuracy of an entry.

4.5. Calculations and the rounding of numbers

A. It is acceptable to round numbers up or down when performing calculations.

B. Round up when the digit to the right of the last significant figure is greater than or equal to five. Round down when this digit is less than five.

i. The last significant figure is always the last digit present in a specification.

C. Examples:

i. The specification is >99%. A result is 98.5%. Round up to 99%.

ii. The specification is >99%. A result is 98.4%. Round down to 98%.

iii. The specification is >88.5%. A result is 88.54%. Round down to 88.5%.

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SECTION:

I. Purpose

To describe the requirements for development and management of Master Manufacturing Records that are essential for uniformly from batch to batch and production of safe, quality dietary supplement product

II. Scope

The requirements for Master Manufacturing Records apply to all finished dietary supplement products.

III. Reference

Department of Health and Human Services
Food and Drug Administration
21 CFR Part 111
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or
Holding Operations for Dietary Supplements, Final Rule, Source: 72 FR 34942, June 25, 2007

IV. Responsibilities

A. The Quality Unit must ensure that Master Manufacturing Records are developed and maintained for each unique formulation and batch size of every dietary supplement produced.
B. The Quality Unit must ensure that Master Manufacturing Records are maintained current, and that any changes to these records are made in accordance with the requirements of the company's change control procedure to ensure that changes are properly documented, communicated, and approved prior implementing the changes.

V. Procedure

A. Master Manufacturing Records must be developed and maintained as controlled documents containing:

1. Master Manufacturing Record Number
2. Product specifications identified
3. Product Name
4. Product Code
5. Effective Date
6. Dated author's signature
7. Dated approval signature

B. The Master Manufacturing Record must be reviewed and approved by the Quality Control Unit prior to production of the first lot of new products or whenever a change has been made to a formula or any part of the Master Manufacturing Record. Review and approval of the Master Manufacturing Record must include comparison to the finished product label to ensure label claims will be met through the production process outlined in the Master Manufacturing Record.

C. Master Manufacturing Records Must:

1. Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement, and that the dietary supplement is packaged and labeled as specific in the Master Manufacturing Record.
2. Establish controls and procedures to ensure that each batch of dietary supplement meets the specifications identified.

D. Master Manufacturing Record must include:

1. The name of the dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size.
2. A complete list of components to be used.
3. An accurate statement of the weight or measure of each component to be used.
4. The identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label, and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement.
5. A statement of any intentional overage amount of a dietary ingredient.
6. A statement of theoretical yield of a manufactured dietary supplement expected at each point, step or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement, and the expected yield of the finished dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary, and material review is required to determine the disposition of the product.
7. A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label.
8. Written instructions, including the following:
   a. Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement, and that the dietary

BLISTERPACK PRO	SOP LOT/ BATCH NUMBERING SYSTEM	SOP #	004L#S
		Revision #	001
		Implementation Date	06/19/19
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SOP Author:	Samir / Surinder Gidha	Q.A. Approval Signature:	
		Management Approval Signature:	

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I. Purpose

1.1. To describe the Lot/Batch numbering system for Blister pack pro.

II. Scope

2.1 It is the responsibility of Production to assign the lot number for the specified production facility according to the procedure defined in this document.

2.2. It is Quality Assurance's responsibility to verify the assigned lot numbers on the label for Blisterpack Pro.

III. Responsibilities

3.1. Production and quality assurance

IV. Procedure

4.1. The lot number contains 7 digits (YYMMDD0)

4.2. 1st two digits is year(yy)

4.3. 2nd two digits is month (MM)

4.4. 3rd, digits are the designated Julian date. (DD)

A. May 28 = 148 on the Julian calendar.

4.5. 4th digit is the department or process designation.

A. B = Bottles (capsules tablets or powders)

B. C = Cans

C. D = Dry Blend

D. F = Roll Stock Film

E. L = Liquid Blend

F. P = Individual Pouches

E. 0 = Tablets Revision #

V. Record Keeping

5.1. Not Applicable

Standard Operating Procedure

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SECTION:

I. Purpose

This document describes the aseptic process for weighing and blending of raw ingredients for each product needed for stock inventory or custom orders.

II. Scope

This procedure is intended to put in place a controlled system for BPP production employees to follow in order to produce all BPP stock products and custom formulas so that quality is maintained, and contamination is avoided.

III. Materials

1. Raw materials per order
2. GBK 70A Scale (weigh station)
3. Blender/mixer
4. Sterilized stainless steel drums.
5. 7 gallon plastic tubs for weighing
6. Gloves, hair net, lab coat/ and or body suit
7. Industrial cleaner for cleaning equipment
8. Alcohol for sterilization
9. Scoop utensils
10. Face mask
11. Safety Glasses

IV. Procedure

1. Prepare area and equipment for blending:
   A. Be sure you have gloves, hairnet, and lab coat on.
   B. Clean and sterilize the blending machine and all its parts.
   C. Clean and sterilize the weigh station scale.
   D. Clean and sterilize supplies to be used for transferring material from scale to blender to stainless steel drum.
   E. Clean and sterilize stainless steel drums to transfer blended ingredients for encapsulating.

Note: Make sure to always keep lids on all drums to prevent contamination of material or sterilized equipment.

2. Follow the batch production run form for product to be made:
   A. Collect all raw ingredients needed for order from raw materials inventory and bring to weigh station.
      1. Use pallet jack to transfer material.
      2. When blending is complete, be sure to have inventory personnel adjust raw materials inventory.

B. Follow formula on the production run form and weigh out each ingredient into a weigh container. Do this for the number of batches required to fulfil the total kg per production run.
C. Adjust all the guides to bottle size to be filled.
D. Retrieve the correct size and number of bottles and caps per order.
E. Load the descrambler with bottles and caps holder with caps.
F. Retrieve cotton and seal as requested on order and load machine.
G. Setup parameters

3. Bottling:
   A. Once all settings have been placed for the batch run, fill the container where the capsules belong.
   B. Start the start bottling machine.
   C. Continue to fill the descrambler with bottles, cap holder with caps, capsule filler with capsules of product as needed.
   D. Watch all areas of the line to make sure no clogging happens, and no melting of bottles happen.
   E. Unload bottles on the end and pack up into case packs.
   F. Monitor form and checks to perform.

Note: Be sure to spray down gloves with alcohol any time you break or touch anything separates from the process

V. Related Documents

Production Run Form

BLISTERPACK PRO	SOP QUALITY CONTROL PROGRAM	SOP #	2001QCP
		Revision #	001
		Implementation Date	04/09/2020
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SOP Author:	Surinder Gidha	Q.A. Approval Signature:	
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I. Purpose

1.1. To outline the organization and function of the Blister pack pro LLC Quality Control Program.

II. Scope

2.1. The Quality Control Program established the Quality duties, responsibilities, and authorities for the Quality Control Department with the Blister pack pro organization.

III. Responsibilities

3.1. The overall responsibility of the Quality Control Program and Quality Control Department is defined and maintained by the Compliance/Regulatory Affairs Manager, independent from production.

IV. Procedure

4.1. The Quality Control Department of Blisterpack Pro has the responsibility and authority for the approval or rejection of:

A. Quality Processes

B. Specifications

C. Component

D. Quality Procedures

E. Quality Controls

F. Tests

G. Results

H. Deviations

4.2. Documentation Approval for the following requirements:

A. Supplier Qualification

B. Raw Materials, Packaging Components, Labels, In-Process Materials and Finished Products specifications.

C. Managing change to documents, equipment, processes.

D. Training and implementation of quality control requirements.

E. Customer complaints, corrective of actions and follow-up.

F. Procedures or specifications that may have an impact on the identity, strength, quality, or purity of the products.

4.3. To ensure product integrity and specification compliance, the operations of the QC Department include, but are not limited to:

A. Sample acquisition and control.

B. Testing and scheduling materials and products for analytical, physical, stability, and microbiological examination.

C. Inspection of all manufacturing and packaging operations.

4.4. Review of production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

4.5. Ensures that testing methodologies, specifications, formulations, and SOPs are current and adhered to.

4.6. Contract laboratories may be used to establish any or all the following: purity, microbiological and vitamin and mineral assays as requested by the customer. Labs must be an FDA licensed facility. Records will be maintained of data derived from all specified tests.

4.7. All products shall bear an expiration or best by date of up to two years. Blisterpack Pro generally produces products that meet the specifications of our customers and relies on information from the customer regarding extended shelf-life.

4.8. Establishment and control of return procedures for finished products.

V. Record Keeping

5.1. Not Applicable