1.0 Purpose

This procedure describes the process of creating and approving a Master Batch Record and issuing a Batch Production Record.

2.0 Scope

This procedure applies to all products manufactured by Ion Nutritional Labs.

3.0 Responsibility

3.1 R&D is responsible for meeting the customer's product requirements, creating product profiles, test details and test tickets, preparing weigh and mix orders, and creating supplement facts panels (or equivalent).

3.2 Planning personnel are responsible for creating packaging profiles.

3.3 DC is responsible for preparing MBRs for approval, issuing and distributing BPRs, maintaining MBRs, and storing BPRs for the required retention period.

3.4 Quality is responsible for approving all MBRs and BPRs.

4.0 Definitions

4.1 **MBR** – Master Batch Record; A compilation of documents and forms that identify all pertinent instructions, process steps, and specifications required to manufacture a product

4.2 **BPR** – Batch Production Record; An accurate reproduction of the MBR that is issued to production for each batch of product manufactured, which will be used to record the

manufacturing process steps in its entirety

4.3 **Product Profile** – Document which establishes a product's components, in-process specifications, finished product specifications, and stability requirements which will ensure the identity, purity, strength, and composition of the product

4.4 **Packaging Profile** – Document which establishes a product's packaging components, in-process packaging specifications, finished product packaging specifications, and all other information pertinent to the product for which the packaging profile has been written

4.5 **FPTT** – Finished Product Test Ticket; an internal COA that contains the finished product specifications and is used to record finished product test results

4.6 **FPTD** – Finished Product Test Details; document which provides detailed instructions for the preparation of standard and sample solutions for the required analytical tests and the assay calculation

4.7 **cGMP** – Current Good Manufacturing Practice

4.8 **Batch/Lot Number** – Any distinctive group of numbers from which a complete history of the manufacturing, packaging, labeling, and/or holding of a batch/lot number can be determined

4.9 **Product Type** – Regulatory classification and physical presentation of finished product (e.g. dietary supplement, pet product, drug, etc.)

4.10 **Dosage Form** – Regulatory classification and physical presentation of finished product (e.g. coated tablets, uncoated tablets, chewable tablets, capsules, powders, liquids, etc.)

4.11 **Formula Number** – a unique identification number assigned to each master formula and referenced within a product SKU

4.12 **Product SKU** – a unique identification number assigned to a customer and product

4.13 **Purchase Order** – A purchase, sales, or fulfillment order that has been approved by senior management and distributed by accounting, which initiates the creation of an MBR

4.14 **QC** – Quality Control

4.15 **QS** – Quality Systems

4.16 **R&D** – Research and Development

4.17 **DC** – Document Control

4.18 **PDT** – Product Detail Tag

4.19 **Redzone (RZ)** – a software application used to collect data during the production process; used to track production data, as well as cGMP data

4.20 **Data Sheet** – an RZ component of the RZ Compliance Module, configured to collect data

4.21 **PQC** – Process Quality Check: refer to SOP B-905 Quality Inspection Process

4.22 **PQV** – Process Quality Verification; refer to SOP B-905 Quality Inspection Process

5.0 References

5.1 C-403, SOP, Change Control Procedure

5.2 C-502, SOP, Record Storage, Retention, and Destruction

5.3 C-707, SOP, Critical Control Point Specifications

5.4 D-401, SOP, New Product Documentation Requirements

5.5 D-501, SOP, Stability Program for Finished Products

5.6 B-112-F1, Form, Master Case Label Request Form

5.7 C-104-F1, Form, Checklist – Tablet

5.8 C-104-F2, Form, Checklist – Gummies

5.9 C-104-F3, Form, Checklist – Capsule

5.10 C-104-F4, Form, Checklist – Powder

5.11 C-104-F5, Form, Checklist – Liquid

5.12 C-104-F6, Form, Batch Release Form – Tablet

5.13 C-104-F7, Form, Batch Release Form – Gummies

5.14 C-104-F8, Form, Batch Release Form – Capsule

5.15 C-104-F9, Form, Batch Release Form – Powder

5.16 C-104-F10, Form, Batch Release Form – Liquid

5.17 C-104-F11, Form, Tableting Record

5.18 C-104-F12, Form, Coating Record – 48"/60" Coating Pan

5.19 C-104-F13, Form, Coating Record – 80" Coating Pan

5.20 C-104-F14, Form, Coating Record – 24" Coating Pan

5.21 C-104-F15, Form, Encapsulation Record

5.22 C-104-F16, Form, Metal Detection Record

5.23 C-104-F17, Form, Bottling Record – Tablets/Capsules/Gummies

5.24 C-104-F18, Form, Bottling Record - Powders

5.25 C-104-F19, Form, Bottling Record - Liquids

5.26 C-104-F20, Form, Blister Packaging Record

5.27 C-104-F21, Form, Pouching Record

5.28 C-104-F22, Form, Labeling Record – Label/Shrink Sleeve

5.29 C-104-F23, Form, Labeling Record – Carton

5.30 C-104-F24, Form, Labeling Record – Display Tray

5.31 C-104-F25, Form, Bulk Packaging Record – Tablets/Capsules

5.32 C-104-F26, Form, Bulk Packaging Record – Powder

5.33 C-104-F28, Form, Powder Sieve Form

5.34 C-104-F29, Form, Roller Compaction Record

5.35 C-104-F30, Form, Banding Record

5.36 C-104-F31, Form, Gummy Record

5.37 C-104-F32, Form, Bulk Packaging Record – Blisters/Pouches

5.38 C-104-F33, Form, Powder Organoleptic Qualification

5.39 C-104-F34, Form, Submersion Leak Test Record

5.40 C-707-F1, Form, CCP 1 – Blending (Absence of Foreign Material and Bulk Density)

5.41 C-707-F2, Form, CCP 2 – Tableting (Compression Startup Check)

5.42 C-707-F3, Form, CCP 2 – Encapsulation (Encapsulation Startup Check)

5.43 C-707-F4, Form, CCP 4 – Metal Detection (Manual)

5.44 C-707-F5, Form, CCP 4 – Metal Detection (Inline)

5.45 C-707-F6, Form, CCP 4 – Metal Detection (Insight Throat)

5.46 C-707-F7, Form, CCP 3 – Dosage Delivery

5.47 C-707-F8, Form, CCP 5 – Blister Packaging Startup

5.48 C-707-F9, Form, CCP 6 – Tank Sampling

5.49 C-707-F10, Form, CCP 7 – Liquid Weight Verification

5.50 C-707-F11, Form, CCP 8 – Pouch Packaging Startup

5.51 C-707-F12, Form, CCP 9 – Gummy Blend Brix Record

5.52 C-707-F13, Form, CCP 10 – Gummy Deposition Checks

5.53 C-707-F14, Form, CCP 11 – Pre-Curing

5.54 C-707-F15, Form, CCP 12 – Post-Curing

5.55 D-401-F2, Form, Finished Product Test Ticket - Internal Certificate of Analysis

5.56 C-111, SOP, Redzone General Use

5.57 C-107, SOP, Redzone Reviewer Activities

5.58 B-905, SOP, Quality Inspection Process

6.0 Procedure

6.1 Process Overview

6.1.1 DC creates MBR for each specific product. The MBR includes a checklist and batch release form specific to that MBR. The checklist ensures accountability for all necessary components of the MBR.

6.1.2 DC issues a BPR for each batch produced based on the MBR checklist for that product.

6.1.3 MBR checklists identify all components and forms required as part of the MBR. If a form and / or MBR component has a Redzone datasheet approved for use to collect that same information, the MBR checklist will reference that Redzone datasheet.

6.2 Redzone

6.3 Redzone is a software application used to collect data during the production process. Redzone is not available for all data collection. The use of Redzone requires verification activities covered by SOP C-107 Redzone Reviewer Activities prior to use in our facility.

6.3.1 Forms provided in the MBR / BPR provide instructions for the collection of data in the batch record. The forms also serve as a backup documentation option if the Redzone data sheets are not available for use. Use Redzone data sheets as the preferred method for recording data if available. When Redzone data sheets are not available, use the associated forms.

6.4 Creating a Customer Specific MBR

Note: For certain products that contain multiple forms of packaging and/or supplements (i.e. a pouch that contains a mixture of different tablets/capsules), product specific forms will be created to ensure that all aspects of the product requirements are captured. These forms will only pertain to the specific product that the form was created for and will follow the same guidelines as the generic batch forms.

6.4.1 DC will receive an approved purchase order that requests a new product to be manufactured. DC will also receive a batch order from Scheduling, specifying

the batch number and batch size for each approved purchase order. Once both of these items have been received, an MBR can be created.

6.4.2 Each MBR is designated by product type and dosage form based on the customer order.

6.4.3 DC will prepare the relevant checklist (Forms C-104-F1 to C-104-F5) according to the requested product type and dosage specified on the provided purchase order. This checklist is a guide to ensure that all necessary forms are included in the MBR.

6.4.4 The checklist identifies the following information:

6.4.4.1 Customer Name

6.4.4.2 Product Name

6.4.4.3 Batch Number

6.4.4.4 Batch Quantity

6.4.4.5 Packaging Type

6.4.4.6 Product SKU (or formula number if more than one SKU will be included in an MBR)

6.4.4.7 A complete list of all documents, specifications, and forms that pertain to the specified product type and dosage.

Note: All forms on the list may not be required for each MBR. When issuing the BPR, DC will mark with a √ which forms are to be included based on customer and internal requirements.

6.4.5 DC will prepare the relevant Batch Release Form (Forms C-104-F6 to C-104-F10) as per the checklist. This form consists of the following sections:

6.4.5.1 Batch Release Requirements – ensures that the correct packaging has been used, the correct printed packaging components have been used, and all documentation is complete, accurate, and meets finished product specifications

6.4.5.2 Quality Control Testing – ensures that the finished product meets finished product specifications (refer to SOP D-401 New Product Documentation Requirements), reserve samples have been collected, and the Certificate of Analysis has been completed and attached.

6.4.6 DC will prepare a Master Sampling Plan for the specified product. This form will outline the sample pull times and amounts required to complete finished product testing.

6.4.7 DC will add the approved Product Profile for the specified product. This product profile will be reviewed against the customer purchase order (or equivalent) to ensure that all customer requirements are correct. Product profiles are checked for accuracy and compliance by R&D and Quality and issued as a controlled document.

6.4.8 DC will add the approved FPTD (Form D-401-F1-XXXXXXXX), FPTT (Form D-401-F2-XXXXXXXX), and Ingredient Addition Verification and Results Form.

6.4.9 DC will retrieve a Weigh and Mix Order for the specified product with the batch size that has been provided. All sections of the Weigh and Mix Order are checked for accuracy and compliance by R&D and Quality, signed and dated by R&D, approved by R&D or Quality, and issued as a controlled document. This document contains the manufacturing information for the specific batch and quantity as per the purchase order and batch order. The Weigh and Mix Order consists of the following sections:

6.4.9.1 Changeover Checklist – ensures cleanliness and proper setup of all equipment and ancillary items, and that rooms are in compliance

6.4.9.2 Master Formula – ensures that the name, ID#, and weight/volume of each component to be used as described by the Master Formula

6.4.9.3 Weigh and Mix Instructions – written mixing/blending instructions

6.4.9.4 Weigh and Mix yield – ensures that all ingredients have been added and are accounted for as dispensed

6.4.9.5 Weigh and Mix Order Notes – blank page for real-time entries of batch information as required during execution of manufacturing

6.4.10 DC will prepare Master Reconciliation Sheets for the specified product. This sheet will contain all relevant sections required to reconcile the batch throughout the manufacturing process, with a reconciliation worksheet for each stage of the manufacturing process.

6.4.11 DC will prepare a Product Detail Tag, which outlines relevant product information such as SKU, batch number, and product cleaning level required.

6.4.12 DC will prepare the relevant Critical Control Point Forms (C-707-F1 through C-707-F15) and add to the MBR for the specified product and dosage form (refer to SOP C-707 Critical Control Point Specifications). These forms identify critical quality control points during manufacturing process steps (e.g. blending, tableting, encapsulating, liquid filling, pouching, blistering, gummy manufacturing).

6.4.13 DC will prepare a Tableting Record (Form C-104-F11) and add to the MBR as specified for coated and uncoated tablets. This form identifies the product specifications for the tableting process, a record of the tableting run, and the tablet yield.

6.4.14 DC will prepare a Coating Record (Forms C-104-F12 through C-104-F14) and add to the MBR as specified for coated tablets. This form identifies the product specifications for the coating process, the coating pan parameters, the tablet coating yield, and a coated tablet AQL inspection form. When applicable, coating mix instructions will also be provided. Coating mix instructions are created by R&D and are specific to the type of coating to be used.

6.4.15 DC will prepare an Encapsulation Record (Form C-104-F15) and add to the MBR as specified for capsules. This form identifies the product specifications for the encapsulation process, a record of the encapsulation run, the capsule yield, and the capsule AQL inspection.

6.4.16 DC will prepare a Banding Record (Form C-104-F30) and add to the MBR for liquid capsules. This form identifies the product specifications for the banding process, a record of the banding run and hold times after banding.

6.4.17 DC will prepare a Bottling Record (Form C-104-17 through C-104-F19) and add to the MBR as specified. This form identifies the product specifications for packaging components and a record of the bottling run.

6.4.18 If the product is to be packaged in blisters, DC will prepare a Blister Packaging Record (Form C-104-F20) and add to the MBR. This form identifies the product specifications for blister packaging components and a record of the blister packaging run.

6.4.19 If the product is to be packaged in pouches, DC will prepare a Pouching Record (Form C-104-F21) and add to the MBR. This form identifies the product specifications for pouch packaging and a record of the pouching run.

6.4.20 DC will attach the approved Master Label File to the MBR as specified. If the Master Label File is not yet available or if the product is to remain unlabeled, a Supplement Facts sheet will be added to the MBR. The Label Master File must

be added prior to starting labeling operations. When possible, both the label master and the supplement facts should be added to the MBR.

6.4.21 DC will prepare a Labeling Record (Form C-104-F22 through C-104-F24) and add to the MBR as specified. This form identifies the product specifications for labels, shrink sleeves, cartons, display trays, and all other tertiary packaging components, and a record of the labeling run.

6.4.22 DC will prepare a Bulk Packaging Record – Tablets/Capsules (Form C-104-F25) and add to the MBR as specified for tablets and capsules. This form will be used only if the product is to be shipped in bulk.

6.4.23 DC will prepare a Bulk Packaging Record – Powder (Form C-104-F26) and add to the MBR as specified for powders. This form will only be used if the product is to be shipped in bulk.

6.4.24 DC will prepare a Bulk Packaging Record – Blisters/Pouches (Form C-104-F32) and add to the MBR as specified for powders. This form will only be used if the product is to be shipped in bulk.

6.4.25 DC will prepare a Gummy Record (Form C-104-F31) and add to the MBR as specified for gummy products. This form identifies product specifications for gummies, gummy production run record, and gummy yield.

6.4.26 DC will prepare all other supplemental forms based on the product requirements, such as:

6.4.26.1 Roller compaction form (C-104-F29)

6.4.26.2 Powder sieve form (C-104-F28)

6.4.26.3 Powder Organoleptic Qualification (C-104-F33)

6.4.26.4 Master case label request form (B-112-F1)

6.4.27 DC will attach any other documents that contain additional details or customer requirements.

6.4.28 DC will complete the top section of all forms and the required entries as indicated on the forms.

6.4.29 DC will create a master file with the customer name, product name, and product SKU. The MBR will be reviewed and approved by Production, R&D, DC, and Quality.

Note: for products that contain allergens, a red folder is to be used.

6.4.30 All revisions to the MBR will be tracked and performed in accordance with SOP C-403 Change Control Procedure.

6.5 For products that are packaged per order, the manufacturing portion of the MBR will contain only a formula number and not an associated product SKU. When a new packaging requirement is received, a Packaging Packet will be created, to include the packaging profile, and added to the MBR as a supplemental section. This will contain the Product SKU.

6.5.1 A packaged per order MBR can contain multiple product SKUs.

6.6 Creating a BPR

6.6.1 DC will copy all pages of the MBR to issue the BPR as requested. The BPR is an accurate reproduction of the MBR.

6.6.1.1 For non-drug products, blue paper will be used for the BPR for the first manufacturing order.

6.6.1.2 For drug products, green paper will be used for the BPR, for every batch issued.

6.6.2 For single batches, a batch number will be assigned to the BPR according to the following examples:

Example: 220001, where:

22 – Last two digits of the year in which the batch will be manufactured

0001 – Sequential number of scheduled sales order in the ERP System. This number starts at 1 and will continue sequentially for the entire calendar year. This number will start back at 1 when the following year begins.

6.6.3 For a large order, or Super Batch, that is to be split into multiple blends, the super batch will be assigned one batch number as outlined above, with trailing sequential numbers to signify a campaign run.

Example: 220001-01, where:

22 – Last two digits of the year in which the batch will be manufactured

0001 – Sequential number of scheduled sales order in the ERP System

01 – First batch in a campaign of multiple batches for one sales order (super batch)

For example: Two batches created for one sales order with the batch number of 220001 will be coded as follows:

Batch 1: 220001-01

Batch 2: 220001-02

6.6.4 Along with the Ion batch number, a Julian system lot number may also be assigned upon customer request.

6.6.5 For batches that contain multiple SKUs, the batch number will be separated with a letter designation.

For example: Batch 220001 contains two SKUS. The batch will be coded as follows:

Packaging SKU 1: 220001A

Packaging SKU 2: 220001B

Additional example: Batch 220003-02 contains two packaging SKUs. The batch will be coded as follows:

Packaging SKU 1: 220003-02A

Packaging SKU 2: 220003-02B

Note: Customer lot numbers will be added as requested by the customer.

6.6.6 DC will record the batch number in the electronic batch log and ensure that the batch number is reflected on each page of the BPR and recorded in the batch issuance spreadsheet, unique to each formula.

6.6.7 If a known allergen is listed on the label or supplement facts sheet, DC will stamp each page of the BPR with a red ALLERGEN stamp and affix an allergen sticker to the front page of the BPR.

6.6.8 Batches that are to be incorporated into the stability program each month will have stability sample requirements marked when issuing batch records as per SOP D-501 Stability Program for Finished Products.

6.6.9 DC will indicate with a √ on the checklist all required forms included in the packet, sign and date the packet, and submit the completed BPR to Quality for approval.

6.7 Cancelling a Batch Number

6.7.1 A batch record can be cancelled if there are changes to the schedule, a customer cancels their order or requests changes, or an error is discovered.

6.7.2 The BPR is returned to DC for cancellation.

6.7.3 DC will document on the electronic batch issue log and on the MBR log sheet that the batch was cancelled.

6.7.4 Once issued, a batch number may not be reassigned to another batch.

6.8 Maintaining Executed BPRs

6.8.1 Executed BPRs are filed and maintained by DC as per SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/15/10	New	-	-
1	01/20/11	Added forms to SOP	-	-
2	08/15/11	Changes in forms attached to SOP	-	-
3	01/24/12	Made some minor changes	-	-
4	09/14/12	Clarified and reorganized SOP. Changed format and title. Revised forms. Provided clarification to ensure label standard is included.	12-139	V. Iltcheva
5	09/22/14	Updated format. Made major changes.	14-0602	V. Iltcheva
6	05/12/15	Updated SOP to include liquid packaging.	15-0420	M. Wienke
7	12/08/15	Updated SOP to include packaged per order MBR specifications and packaging packet specifications. Organized SOP. Revised all attached forms.	15-1177	V. Iltcheva
8	11/11/16	Added note for the addition of product specific forms.	16-1020	K. Burris
9	09/10/18	Complete rewrite to reflect new ERP requirements. Obsolete processes removed. All forms revised and renumbered per ERP System. Added new forms.	18-0302	K. Burris
10	06/24/19	Added form C-104-F30. Removed reference to master formula and finished product specification sheet. Added note for customer specific lot numbers. Updated multiple forms to remove obsolete information.	19-0400	K. Burris
11	01/04/21	Added forms for gummy manufacturing.	CC-21-0001	P. Wilson
12	05/15/23	Clarified SOP throughout. Updated form references. Updated referenced SOP names. Added new forms and revised existing forms.	CC-23-0250	K. Burris
13	03/02/24	Add form C-104-F34 submersion leak test record to reference section.	CC-24-0108	K. Burris