1.0 Purpose

The purpose of this procedure is to define the process for the review of batch production records and to specify the manner in which finished products are released for shipment.

2.0 Scope

This procedure applies to all products manufactured and/or packaged at Ion Nutritional Labs.

3.0 Responsibility

3.1 It is the responsibility of Quality to follow this procedure.

3.2 It is the responsibility of Quality Management to implement this procedure and to ensure that the procedure is being followed.

4.0 Definitions

4.1 **BPR** – Batch Production Record; an accurate reproduction of the MBR and is a compilation of documents and forms issued to production that contains/identifies all of the pertinent instructions/process steps/specifications necessary to manufacture a batch of product

4.2 **MBR** – Master Batch Record; a compilation of documents and forms that contains/identifies all of the pertinent instructions/process steps/specifications necessary to manufacture a product

4.3 **Product Profile** – a document with the details of the finished product specifications, unique for each approved product

4.4 **Product SKU** – Stock Keeping Unit; the unique identification number assigned to a product/customer

4.5 **OOS** – Out of Specification

4.6 **QC** – Quality Control

4.7 **DC** – Document Control

4.8 **COA** – Certificate of Analysis

4.9 **COC** – Certificate of Compliance

4.10 **COM** – Certificate of Manufacture

5.0 References

5.1 C-201, SOP, Deviation and Investigation Procedure

5.2 C-104, SOP, Master Batch Record and Issuance of Batch Production Record

6.0 Procedure

6.1 Quality will perform a review of the BPR to ensure that all critical control points of the processes have been documented and have met the specified ranges and yields.

6.2 Each page will be reviewed for data integrity.

6.2.1 Ensure that all components and raw materials used in the batch have been released.

6.2.1.1 A release report must be generated for each batch of product, which outlines all raw material and packaging component lots used to create the batch, and the release status of each lot. The batch may not be

released unless all raw materials/components display a status of Released.

6.2.2 Ensure there are no outstanding investigations.

6.2.2.1 Should the batch be the subject of an investigation, the investigation must be closed and added to the BPR prior to release.

6.3 Verify that all calculations are correct and all signatures/initials/dates are present and legible.

6.4 Ensure that all results, yields, and reconciliations fall within the acceptance criteria stated in the BPR.

Note: If a reconciliation yield is out of specification but a justified explanation is evident, indicate in the Comments section of the yield page the information regarding the adjustment and justification for release. If a justified explanation is not evident, a deviation will be opened and an investigation will be performed per SOP C-201 Deviation and Investigation Procedure.

6.5 Verify that all corrections have been documented properly.

6.6 Ensure that all labeled/cartoned/pouched/blistered products have a representative sample of the printed packaging component affixed in the BPR for traceability.

6.7 Ensure that there is a master case label and pallet label (if applicable) affixed in the BPR for traceability.

6.8 Ensure that all batches contain a copy of the product coding printed or stamped onto the primary packaging container placed in the BPR for traceability. Verify the batch number and shelf life is consistent with the information provided in BPR.

6.9 Review the entire BPR to ensure that it is complete, all required information is entered or attached, and all signatures/initials/dates/times are present.

6.10 Complete the Final QC Yield to verify that the order has been fulfilled and falls within the allowable range. If outside of the specified range, forward this information to Production for review.

6.11 All released batches require a COA. A copy of the COA will be sent to the customer or with the shipment unless another method has been requested by the customer.

6.11.1 Quality will create a COA from the approved analytical testing results for each batch.

6.11.2 The COA will be based on the product's testing and specifications.

6.12 Quality will sign the COA and place it in the BPR.

6.13 A COC/COM/additional release reports may be generated upon customer request.

6.14 Indicate the release or rejection of the batch and complete the relevant Batch Release and Reconciliation Form per SOP C-104 Master Batch Record and Issuance of Batch Production Record.

6.15 A Release Letter will be generated and provided to the customer upon release.

6.16 The batch status will be changed to released in the ERP system, which will allow for the generation of a delivery note.

6.17 Once the product is released, the In-Process/Pending Release tag will be removed from the pallets. The Shipping Department will be made aware that the batch is released and the product is now approved for shipment.

6.18 If the product is rejected, replace the In-Process/Pending Release tag with a Hold tag and move the pallet to the designated holding area until an investigation is completed and a disposition has been obtained.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/20/10	New	-	-
1	07/26/10	Added Sections 5.9 and 5.10	-	-
2	09/13/12	Clarified and reorganized SOP. Changed format and title. Added details regarding label standard requirements.	12-138	V. Iltcheva
3	09/12/14	Updated SOP format. Added instructions for Ion Stock Formulations/Packaged per Customer orders. Made some minor changes to reflect current practices.	14-0696	M. Wienke
4	08/24/16	Biennial review – add reference to CFR and SQF, updated orders of steps for batch release, changed process when packaging Ion Stock orders for customer	16-0777	E. Hasanbasic
5	09/23/19	Scheduled review: updated procedure to reflect current processes.	19-0695	K. Burris
6	09/18/23	Scheduled review: changed logo and footer. Added release report requirements. Added investigation requirements. Added blisters and pouches to scope of required samples. Added initials to scope of review requirements. Added release requirements in the ERP and subsequent activities.	CC-23-0468	K. Burris