HBI Ion Labs	Standard Operating Procedure Packaging Procedure	SOP Number B-904	Revision ~~9~~ 10 ①
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Written by/ Date 07/23/25	Reviewed by/ Date JAC 07/31/25	Approved by/ Date 07/31/25
Title: Senior Production Manager	Title: QA Audit Supervisor	Title: Quality Director

1.0 Purpose

The purpose of this procedure is to outline all packaging processes performed at Ion labs, Inc.

2.0 Scope

This procedure applies to all packaging operations at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Production (Packaging) Personnel to strictly follow this procedure.

3.2 It is the responsibility of Production Management to implement this procedure and to ensure that all involved personnel have been properly trained to follow this procedure.

3.3 It is the responsibility of QA Inspectors to ensure that this procedure is being followed.

4.0 Definitions

4.1 **BPR** – Batch Production Record

4.2 **PITT –** Pallet Inspection Transfer Ticket

4.3 **QA –** Quality Assurance

4.4 **PPE –** Personal Protective Equipment

4.5 **CCP –** Critical Control Point

4.6 **cGMP –** Current Good Manufacturing Practices.

① Wrong entry VBE 08/20/25

5.0 References

5.1 A-108, SOP, Good Manufacturing Practices and Personal Hygiene

5.2 C-707, SOP, Critical Control Point Specifications

5.3 B-905, SOP, Quality Control Inspection Process

5.4 C-105, SOP, Protocol and Report Documentation Requirements

5.5 E-803, SOP, Inspection of Palletized In-Process and Finished Product

5.6 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

5.7 G-207, SOP, Calibration Verification and Operation of Scales

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

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

6.0 Procedure

6.1 Packaged Only Product Packouts

6.1.1 For packaged only batches, previously manufactured product is received and issued as a raw material.

6.1.2 Premade product will be tested for microbial contamination at a minimum. Additional testing will be performed as requested by the customer or as deemed necessary by the QC Laboratory.

6.1.3 Single instance production runs of premade product will be managed through protocol unless otherwise stated. Refer to SOP C-105 Protocol and Report Documentation Requirements.

6.2 Issuance and Return of Packaging Components

6.2.1 All required packaging components as outlined in the BPR must be collected from the warehouse and issued to the batch.

6.2.2 After the packaging process has completed, all boxes containing packaging components must be closed well by sealing the internal plastic bag, taping closed the outer container, and/or securing plastic container lids. Once sealed, Production must call a Warehouse employee immediately so that all components can be returned electronically in Batchmaster and physically to the warehouse.

6.3 General Packaging Requirements

6.3.1 Ensure that all packaging areas, equipment, and utensils are clean and that all appropriate cleaning has been documented as outlined in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.

6.3.2 If using a scale, ensure that the calibration has been verified and documented in Redzone. Refer to SOP G-207 Calibration Verification and Operation of Scales.

6.3.3 Check the calibration stickers on all equipment that is to be used to ensure that calibration has not expired. Report any expired calibration to the QA department and remove the equipment from service.

Note: Do not use equipment with expired calibration.

6.3.4 Ensure that the packaging area is clear of all materials from the previous batch. This includes, but is not limited to, the BPR, in-process materials, packaging components, printed packaging, and associated documentation.

6.3.5 Identify the packaging room and equipment with a product detail tag.

6.3.6 Prior to the start of a packaging run, the operator and QA inspector must check all materials and product containers for the following:

6.3.6.1 Check the material ID number against the BPR.

6.3.6.2 Check the description of the material against the BPR.

6.3.6.3 Check the batch number against the BPR.

6.3.6.4 Ensure that the material has been released for use.

6.3.6.5 Ensure that the packaging components have been released or approved by Quality for at risk use.

6.3.6.5.1 An issuance report must be generated prior to room startup which outlines the release status of each lot of packaging material to be used. The QC Laboratory must approve to use at risk any lot of packaging material that is in quarantine status.

6.3.6.6 The operator must verify that the quantity of material available is the correct quantity for the production run.

Note: If any confirmation is not met, notify Production and Quality Management.

6.3.7 If the entire quantity of any component is not in the packaging room at the startup, operator must verify any subsequent delivery and notify QA inspectors to perform additional verification. If a new lot of packaging material is issued to the batch, a new issuance report must be generated and verified.

6.3.8 Personnel and visitors must follow cGMP guidelines as per SOP A-108 Good Manufacturing Practices and Personal Hygiene. Personnel must follow all safety precautions by wearing appropriate PPE.

6.3.8.1 Personnel must be garbed appropriately with frocks and/or lab coats, hairnets, shoe covers and/or dedicated shoes, beard covers (if applicable), dust masks, and gloves.

Note: For powder bottle filling areas only, gloves must be a minimum thickness of 0.08mm. This should help to prevent

contamination of the product due to ripped gloves during the filling process.

6.3.9 All product (excluding certain liquid products) must pass through the metal detector without indication of metal. Refer to SOP C-707 Critical Control Point Specifications.

6.3.9.1 Liquid products are evaluated by product to determine if metal detection can be performed. Due to the nature of some liquid form products, metal detection cannot be performed.

6.3.10 All packaging procedures outlined in the BPR must be strictly followed.

6.3.11 During the packaging process, all reasonable precautions must be taken to ensure that the packaging process does not contribute contamination from any source.

6.3.12 If, during the packaging process, any problem with the packaging equipment occurs, stop the machine and immediately notify the department supervisor to take the necessary action.

6.3.13 The operator performing checks must record initials, date and time that checks are performed and status of each check. If a check reveals an out of specification result, a notation must be made in the BPR of actions taken to correct the issue.

6.3.14 All knives and cutting instruments are to be controlled, cleaned and well maintained. Knives and cutting instruments will be cleaned once a week or during scheduled room cleanings. These instruments will be only issued by the Facility Manager.

6.4 For bulk packaging, follow the requirements that have been specified in the Packaging Profile and BPR.

6.5 Bottling Procedure

6.5.1 The operator performs four bottle checks at startup and every 60 minutes (±15 minutes) excluding shift downtime for breaks, etc. unless stated otherwise in the individual batch record until the end of the bottling run to ensure product quality.

6.5.2 The QA inspector performs an audit of the documents, the manufacturing area to ensure compliance with the batch record and all applicable procedures.. Refer to SOP B-905 Quality Inspection Process.

6.5.3 For tablets and capsules:

6.5.3.1 Verify the bottle count and ensure that the product in the bottle meets all required quality standards.

6.5.3.1.1 Tablets must be consistent in size, color, and shape and must be free of chips, breaks, capping, foreign matter, and discoloration.

6.5.3.1.2 Capsules must be fully locked and consistent in size, color and powder quantity and must be free of folding, dimpling, and tears.

6.5.4 For powders and liquids:

6.5.4.1 Verify bottle fill weight and ensure that the product in the bottle is free of foreign matter and consistent in color.

6.5.5 For gummies:

6.5.5.1 Verify the bottle count and ensure the gummies are consistent in size, color, shape, there is not a lot of excess on the sides, and they are free of foreign matter.

6.5.5.2 Verify scale calibration and document in Red Zone. Gummy count will be verified by weight.

6.5.6 Ensure that the bottle contains space filler as specified.

6.5.7 Ensure that the bottle contains a desiccant or scent tab as specified.

6.5.8 Ensure that a neckband or clear full body sleeve is present and correctly oriented as specified.

6.5.9 Ensure that the cap is threaded and sealed properly. Perform cap torque test as specified in the BPR.

6.5.10 Complete the yield calculation reconciliation in the BPR. Move the packaged product to the designated area until the product is released for shipment or further processing by QA inspector.

6.6 Blistering Procedure

6.6.1 Ensure that Form C-707-F8 CCP 5 – Blister Packaging Startup has been completed and approved before starting the run.

6.6.2 The packaging operator performs three blister checks at startup and every 60 minutes (±15 minutes) unless stated otherwise in the individual batch record until the end of the blistering run to ensure product quality.

6.6.3 The QA inspector performs an audit of the documents, the manufacturing area to ensure compliance with the batch record and all applicable procedures. Refer to SOP B-905 Quality Inspection Process.

6.6.3.1 Verify the blister count and ensure that the product in the blister meets all required quality standards.

6.6.3.1.1 Tablets must be consistent in size, color, and shape and must be free of chips, breaks, capping, foreign matter, and discoloration.

6.6.3.1.2 Capsules must be fully locked and consistent in size, color and powder quantity and must be free of folding, dimpling, and tears.

6.6.3.2 Ensure that the blister cavities are formed uniformly and the foil is sealed with dots notably distinguished and even from each side of the blister cavity.

6.6.3.2.1 Operator will perform a blister submersion leak test at startup and during routine inspections of the blistering process.

6.6.3.3 Ensure that all required blister coding is legible and correct.

6.6.3.4 Complete the yield calculation reconciliation in the BPR. Notify the Warehouse for them to move the packaged product to the designated area until the product is released for shipment or further processing by QA.

6.7 Pouching Procedure

6.7.1 Ensure that Form C-707-F11 CCP 8 – Pouch Packaging Startup has been completed and approved before starting the run.

6.7.2 The packaging operator performs three pouch checks at startup and every 60 minutes (±15 minutes) excluding shift downtime for breaks, etc. unless stated otherwise in the individual batch record until the end of the pouching run to ensure product quality.

6.7.3 The QC inspector performs an audit of the documents, the manufacturing area to ensure compliance with the batch record and all applicable procedures Refer to SOP B-905 Quality Inspection Process.

6.7.4 For tablets and capsules:

6.7.4.1 Verify the pouch count and ensure that the product in the pouch meets all required quality standards.

6.7.4.1.1 Tablets must be consistent in size, color, and shape and must be free of chips, breaks, capping, foreign matter, and discoloration.

6.7.4.1.2 Capsules must be fully locked and consistent in size, color and powder quantity and must be free of folding, dimpling, and tears.

6.7.5 For powders and liquids:

6.7.5.1 Verify pouch fill weight and ensure that the product in the pouch is free of foreign matter and consistent in color.

6.7.6 Ensure that the pouches are formed uniformly and the pouch has no large wrinkles or other visual defects. Pouches must be fully sealed on all sides and properly aligned on all corners.

6.7.7 If needed, a packaging operator or QA inspector will perform a submersion leak test at startup and during routine inspections of the pouching process. Ensure that all required pouch coding is legible and correct.

6.7.8 Complete the yield calculation reconciliation in the BPR. Move the packaged product to the designated area until the product is released for shipment or further processing by QA.

6.8 Labeling, Shrink Sleeving, and Cartoning Procedure

6.8.1 All labels, shrink sleeves, cartons, and display trays must be released by Label Control and issued by the Warehouse, and must be the correct item for the job.

6.8.2 All label and carton part numbers must be verified against the BPR.

6.8.3 A representative sample of the item that is to be used must be affixed in the BPR and confirmed by QA before the packaging process begins.

6.8.3.1 For Labels, Each time a new spool is added to the line, a representative sample from the spool will be examine to ensure it is the correct label and must be affixed to the batch record with the operator's initials and date and time.

6.8.4 Labeling instructions stated in the BPR must be strictly followed.

6.8.5 The packaging operator performs four checks at startup and every 60 minutes (±15 minutes) excluding shift downtime for breaks, etc. unless stated otherwise in the individual batch record until the end of the run to ensure product quality.

6.8.6 The QA inspector performs an audit of the documents, the manufacturing area to ensure compliance with the batch record and all applicable procedures Refer to SOP B-905 Quality Inspection Process.

6.8.7 At the end of bottling, labeling and/or cartoning lines, packaging personnel will visually examine each unit for conformance as detailed below:

6.8.7.1 Bottled product is 100% visually inspected to ensure coding is legible, the batch number is present and correct, and shelf life is present and correct as required by BPR

6.8.7.2 Bottled product is 100% visually inspected for label or shrink sleeve presence on the bottle with no visible wrinkles, and proper orientation on the bottle (refer to Attachment 1 for label orientation).

6.8.7.3 Bottled product is 100% visually inspected for the presence of a neckband or clear full body sleeve as applicable.

6.8.7.4 Cartoned product is 100% visually inspected to confirm carton integrity and elegance. An insert will also be confirmed at this time and if applicable.

6.8.8 A copy of the product coding must be made and placed in the associated BPR.

6.8.9 Complete the yield calculation reconciliation in the BPR. Notify QC and move the packaged product to the designated area until the product is released for shipment by QC. Pallets should be identified with Hold – Pending Release tags.

6.9 Tertiary Packaging and Palletizing

6.9.1 Product will be packed into a master case outlined in the BPR and a master case label will be applied.

6.9.2 Generic master case labels are generated by Production Control personnel and contain the following information at a minimum:

6.9.2.1 Batch number

6.9.2.2 Product name

6.9.2.3 Shelf life

6.9.2.4 Quantity per master case

6.9.3 Customer specific master case labels are generated by Quality Assurance personnel and contain information provided by the customer and outlined in the Packaging Profile and on the Shipping Label Request Form (as applicable).

6.9.4 Master case and pallet labels must be reviewed and approved prior to being applied and a representative sample must be placed in the BPR.

6.9.5 Master cases will be placed onto the pallet as outlined in the BPR and all special palletizing instructions must be followed.

6.9.6 The pallets should be properly identified by a PITT that includes the product name, customer name, batch number, pallet number(s), and quantity. Refer to SOP E-803 Inspection of Palletized In-Process and Finished Product.

6.9.7 Each original white copy of the PITT will be placed in the BPR for accountability.

6.10 After the completion of the production run, cleaning of the room/area and equipment must be performed according to the appropriate procedures and documented as outlined in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.

6.11 Final release of the batch will be dependent on product meeting all required finished product specifications as outlined on the finished product test ticket.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1 02/04/13		New	13-050	V. Iltcheva
2	07/21/14	Updated SOP format. Changed QA to QC. Changed section 7.7, 7.9.1.1.2, and 7.12. Added section 7.8. Changed QC inspection from 30 minutes to 1 hour.	14-0584	V. Iltcheva
3	06/18/15	Added PITT requirements. Added requirements for material confirmation.	15-0524	E. Cummings
4	03/10/16	Added reference to cutting instruments and knives.	16-0216	S. Millar
5	11/10/16	Added requirements to verify any materials brought to packaging rooms. Added inspection sheet.	16-0826	E. Hasanbasic
09/13/19 6		Scheduled review: complete rewrite.	19-0660	K. Burris
7	08/02/21	Added gummy bottling procedure.	CC-21-0307	K. Blozousky
8	10/07/21	Added note in step 6.3.7.1 to specify glove requirements.	CC-21-0376	K. Burris
9	05/20/22	Updated procedure to reflect current practices. Added additional definitions and references. Updated format and logo.	CC-22-0220	K. Blozousky
10	07/11/25	1. Updated Header with current Logo 2. Update references to QC and QC inspectors to QA as appropriate 3. Update 6.5.2, 6.7.3, and 6.8.5 to change the hourly checks to and audit of the documents 4. Update 6.7.7 to include a packaging operator as party that may perform check 5. Update 6.8.2 to include part before number 6. Update 6.8.7 to specify personnel responsibilities at the end of various packaging lines and add "as required by BPR" 7. Update 6.9.3 to read Quality Assurance 8. Update 6.5.1, 6.6.2, 6.7.2 and 6.8.5 to 60 minutes unless specified in BPR 9. Update 6.3.6.5 to specify Quality will release packaging components 10. Remove "and QA inspector" from 6.3.13 and update 6.6.3.2.1 to operator 11. ~~Update 6.5.5.2 to specify to document in Red Zone~~ 12. Update 6.6.3.4 to change from notify QA to WH	CC-25-0277	S. Orlovic

8.0 Attachments

8.1 Attachment 1 – Example of Correct Label Orientation

Attachment 1 – Example of Correct Label Orientation