1.0 Purpose

The purpose of this procedure is to outline the process for liquid encapsulation of product manufactured by Ion Labs, Inc.

2.0 Scope

This procedure applies to all liquid products that require encapsulation at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Production (Liquid Encapsulation) Personnel to follow this procedure.

3.2 It is the responsibility of Facility (Cleaning) Personnel to ensure that all holding drums and lids are wiped down prior to removing from the encapsulation area.

3.3 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.

3.4 It is the responsibility of QC Personnel to ensure that this procedure is being followed.

4.0 Definitions

4.1 **BPR** – Batch Production Record

4.2 **QC** – Quality Control

4.3 **PITT** – Pallet Inspection Transfer Ticket

4.4 **PPE** – Personal Protective Equipment

4.5 **CCP** – Critical Control Point

4.6 **IPA** – 70% Isopropyl Alcohol

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 Inspection Process

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

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

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

5.7 C-707-F3, Form, CCP2 – Encapsulation Startup Check

5.8 C-104-F15, Form, Encapsulation Record

5.9 C-104-F30, Form, Banding Record

6.0 Procedure

6.1 Ensure that the liquid encapsulation room and scoops are clean and that all cleaning has been documented as outlined in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.

6.2 Ensure that the liquid encapsulation room is clear of all evidence of the previous batch.

6.3 Ensure that scale calibration is verified daily and that the designated log book has been filled out. Refer to SOP G-207 Calibration Verification and Operation of Scales.

6.3.1 Check the calibration sticker to ensure that the scale calibration has not expired. Report expired calibration to QC personnel and remove from service.

Note: Do not use expired calibration equipment.

6.4 Identify the liquid encapsulation room with a product detail tag.

6.5 An inspection of the room, equipment, and utensil cleanliness must take place prior to bringing any product into the room. The inspection must be documented in the BPR.

6.6 Prior to the start of a new batch run, the operator and QC inspector must check all materials and product containers for the following:

6.6.1 Check the material ID# against the BPR.

6.6.2 Check the description of material against the BPR.

6.6.3 Check the batch number against the BPR.

6.6.4 Ensure that the blended material has been released by QC.

6.6.5 Ensure that the inner capsule has been released by QC (if applicable).

6.6.6 Ensure that the capsules have been released or approved by QC Laboratory for at risk use.

6.6.6.1 An issuance report must be generated prior to room startup which outlines the release status of each lot of capsules to be used. QC Laboratory must approve to use at risk any lot of capsules that are in quarantine status.

6.6.7 The operator must verify that the quantity of material is available for the job.

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

6.7 Personnel and visitors must follow GMP as per SOP A-108 Good Manufacturing Practices and Personal Hygiene. Personnel must follow safety precautions by wearing appropriate PPE.

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

6.7.2 Operators must change gloves before entering the liquid encapsulation room.

6.8 Liquid Encapsulation

6.8.1 All encapsulation activities are recorded on form C-104-F15 Encapsulation Record and form C-707-F3 CCP-2 Encapsulation Startup.

6.8.2 Make all necessary adjustments to ensure that the capsules meet the current product specifications as outlined in the BPR.

6.8.2.1 Capsule Weight

- Capsule weight ranges are specified in each product profile. Specifications are as follows unless otherwise specified.
    - Minimum Allowed Weight: -10% of target weight
    - Lower Control Limit: -5% of target weight
    - Upper Control Limit: +5% of target weight
    - Maximum Allowed Weight: +10% of target weight

6.8.3 Ensure that the correct capsule size, color, and material are used as specified in the BPR.

6.8.4 Ensure that the capsule length is within the required tolerances as outlined in the BPR.

6.8.5 The encapsulation procedure stated in the BPR must be strictly followed. Keep encapsulation equipment adjusted to maintain all required specifications.

6.8.6 Ensure that form C-707-F3 CCP 2 - Encapsulation Startup Check has been completed by QC and passes all requirements. Refer to SOP C-707 Critical Control Point Specifications.

6.8.7 The operator performs ten capsule checks at startup and every thirty minutes until the end of the encapsulation run to ensure product quality.

6.8.8 The QC inspector performs ten capsule checks as outlined in SOP B-905 Quality Inspection Process to ensure product quality.

6.8.9 During encapsulation, the following steps should be observed.

6.8.9.1 Record the in-process weights in the BPR.

Note: Production Management (with evaluation from R&D and/or QC Laboratory Management) must approve any instance of weights running outside of the specified lower and upper control limits.

6.8.9.2 Record the in-process capsule lengths in the BPR.

6.8.9.3 Ensure that capsules are completely locked with consistent size, color, liquid quantity, and inner capsule (if applicable).

6.8.9.4 Document in the BPR if adjustments are made.

6.9 Banding

6.9.1 All banding activities are documented on form C-104-F30 Banding Record.

6.9.2 Make all necessary adjustments to ensure that capsules meet the current product specification as outlined in the BPR.

6.9.2.1 Ensure appropriate banding glue is applied as specified in the BPR.

6.9.2.2 Ensure the appropriate banding components are used as specified in BPR.

6.9.3 During the banding process, the following steps should be observed:

6.9.3.1 Ensure the banding glue is changed per the hours specified in the BPR.

6.9.3.2 Ensure the capsules are banded correctly and consistently.

6.9.3.3 Check capsules in the vacuum chamber as specified in the BPR. Notify department supervisor/manager of any leaks.

6.9.3.4 Document band adjustments, when applicable.

6.9.4 Hold Time

6.9.4.1 After the banding process, capsules are placed on cleaned/lined trays for drying. Follow and document the hold times as specified in the BPR.

6.9.4.2 Trays/racks must be cleaned per SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment. Trays are to be lined with FDA approved food contact butcher paper. Butcher paper must be disposed after each batch. When the butcher paper is not in use, it must be covered appropriately to prevent cross contamination.

6.9.4.3 Once the capsules have met the required hold time, they will be transferred to a holding container.

6.9.4.4 Verify that the in-process containers are identified with an in-process label that includes the following information:

- Product Name
- Batch Number
- Container Number
- Weight per Container

6.9.5 Completion of the encapsulation process requires the following steps.

6.9.5.1 Place the filled containers with capsules onto the floor scale and record the container weight in the BPR.

Note: All production holding drums MUST be wiped down with IPA on the outside of the drum and lid to remove excess product prior to removing from the encapsulation area.

6.9.5.2 Complete the yield calculation and reconciliation in the BPR and move all in-process containers to the in-process area.

6.9.5.3 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.

6.9.6 After encapsulation, cleaning of the room 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.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	08/16/21	New procedure.	N/A	R. Petrovski
1	05/17/22	Updated procedure to reflect current practices. Added additional definitions and references. Updated format and logo. Added to section 6.9.3. Revised inspection frequencies. Added banding hold time documentation requirements.	CC-22-0219	K. Blozousky