ION LABS	Standard Operating Procedure Encapsulation Procedure	SOP Number B-903	Revision 6
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Written by/ Date	Reviewed by/ Date	Approved by/ Date
Kylee Brozousky 05/17/22	05/18/22	05/20/22
Title: Packaging Supervisor	Title: Production Manager	Title: QA Manager

1.0 Purpose

The purpose of this procedure is to outline the process for the encapsulation of product.

2.0 Scope

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

3.0 Responsibility

3.1 It is the responsibility of 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 compression 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 Control 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

6.0 Procedure

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

6.3 Ensure that 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.

6.4 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.

6.5 Identify the encapsulation room with A product detail tag.

6.6 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.

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

6.7.1 Check the material ID# against the BPR.

6.7.2 Check the description of material against the BPR.

6.7.3 Check the batch number against the BPR.

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

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

6.7.5.1 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.

6.7.6 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.

6.8 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.

6.8.1 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.

6.8.2 Operators must change gloves before entering an encapsulation room.

6.9 Encapsulation

6.9.1 Make all necessary adjustments to ensure that capsules meet the current product specification specified in the BPR.

6.9.1.1 Capsule weight

- Capsule weight ranges are specified in each product profile. Specification is as follows unless otherwise specified.
  - Minimum Allowed Weight: 10% of target weight
  - Lower Control Limit: 4% of target weight
  - Upper Control Limit: 2.5% of target weight
  - Maximum Allowed Weight: 5% of target weight

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

6.9.3 The encapsulation procedure stated in the BPR must be strictly followed. Keep encapsulation equipment adjusted to maintain weight tolerances.

6.9.4 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.

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

6.9.6 The QC inspector performs ten capsule checks at startup and every one hour until the end of the encapsulation run to ensure product quality. Interval based inspections can be adjusted as needed based on risk. Refer to SOP B-905 Quality Control Inspection Process.

6.9.7 During encapsulation, the following steps should be observed.

6.9.7.1 Record the in-process weights in the BPR.

Note: Production Management must approve any instance of weights running outside of the specified lower and upper control limits.

6.9.7.2 Record the in-process lengths in the BPR.

6.9.7.3 Ensure that capsules are completely locked with consistent size, color, and powder quantity.

6.9.7.4 Verify that in-process containers are identified with an in-process label that includes the following information.

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

Note:

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

6.9.9 Completion of the encapsulation process requires the following steps.

6.9.9.1 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 powder prior to removing from the encapsulation area.

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

6.9.9.3 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.

6.9.10 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	06/04/10	New	-	-
1	06/27/11	Made SOP more detailed.	-	-
2	05/10/13	Updated SOP format and title. Removed attachments.	13-366	B. Mosall
3	06/18/15	Updated SOP format. Added requirements for material confirmation.	15-0522	E. Cummings
4	08/27/15	Added note in section 6.9.6	15-0734	E. Cummings
5	09/13/19	Scheduled review: Added capsule length data collection reference. Updated format. Added capsule weight specifications.	19-0659	K. Burris
6	05/17/22	Updated procedure to reflect current practices. Added additional definitions and references. Updated format and logo.	CC-22-0225	K. Blozousky