ION LABS	Standard Operating Procedure Compression Procedure	SOP Number B-902	Revision 6
		Effective Date 07/12/22	Page Page 1 of 6

Written by/ Date	Reviewed by/ Date	Approved by/ Date
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1.0 Purpose

The purpose of this procedure is to outline the process for compression of blended batches.

2.0 Scope

This procedure applies to all blended batches that require compression at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Production (Compression) 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 P

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-F2, Form, CCP 2 – Compression Startup Check

6.0 Procedure

6.1 Ensure that the compression 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 compression 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 Compression personnel will go to the tooling area to get the tooling needed for each run. The tooling attendant will have the tooling ready with dust cups. It is the responsibility of Compression personnel to install the tooling with dust cups prior to and throughout the run. Any damaged dust cups need to be returned to the tooling attendant and any missing dust cups must be reported to supervisor or manager immediately.

6.5 Check the calibration sticker to ensure that the scale calibration and not expired. Report expired calibration to QC personnel.

Note: Do not use expired calibration equipment.

6.6 Identify the compression room with a product detail tag.

6.7 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.

6.8 Prior to the start of a job, the operator and QC inspector must check all materials and product containers for the following:

6.8.1 Check the material ID# against the BPR.

6.8.2 Check the description of material against the BPR.

6.8.3 Check the batch number against the BPR.

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

6.8.5 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.

6.9 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.

6.9.1 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.

6.9.2 Operators must change gloves before entering a compression room.

6.10 Compression

6.10.1 Make all necessary adjustments to the tablet press so that tablets meet the following specifications outlined in the BPR.

6.10.1.1 Tablet Weight

- Tablet 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: 4% of target weight
  - Upper Control Limit: 2.5% of target weight
  - Maximum Allowed Weight: 5% of target weight

6.10.1.2 Tablet Hardness

6.10.1.3 Friability

6.10.1.4 Thickness (if required)

6.10.2 The compression procedure stated in the BPR must be strictly followed. Keep tableting equipment adjusted to maintain specifications.

6.10.3 Ensure that form C-707-F2 CCP 2 – Compression Startup Check has been completed by QC and passes all requirements. Refer to SOP C-707 Critical Control Point Specifications.

6.10.4 During compression, the following steps should be observed.

6.10.4.1 Record the in-process weights on the BPR.

6.10.4.2 Record the in-process hardness on the BPR.

6.10.4.3 Record the in-process thickness (if required) on the BPR.

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

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

6.10.5 If, during the compression process, any problem with the tablet press occurs, stop the press and immediately notify the department supervisor to take the necessary action.

6.10.6 Completion of the compression process requires the following steps.

6.10.6.1 Place the filled containers with tablets on 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 compression area.

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

6.10.6.3 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.

6.10.7 After compression, 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	06/27/11	New procedure.	-	-
1	05/10/13	Updated SOP format.	13-367	B. Mosall
2	06/18/15	Updated SOP format. Added requirements for material confirmation.	15-0523	E. Cummings
3	08/27/15	Added note in section 6.9.5	15-0733	E. Cummings
4	08/27/17	Added section for dust cup inspection/replacement and PM frequency	17-0914	S. Millar
5	03/05/21	Scheduled review: Added section on tooling & dust cups.	CC-21-0089	J. Mireles
6	06/02/22	Updated procedure to reflect current practices. Added additional definitions and references. Updated format and logo.	CC-22-0224	K. Blozousky