
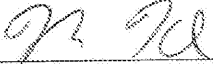
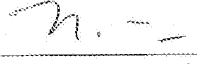
	Standard Operating Procedure		SOP Number B-910	Revision 4
	Weighing and Dispensing Procedure		Effective Date 02/19/26	Page Page 1 of 10
Written by/ Date  01-13-26		Reviewed by/ Date  01-13-26		Approved by/ Date  01/14/26
Title: Warehouse Manager		Title: Chief Operating Officer		Title: QA/QC Director

## 1.0 Purpose

The purpose of this procedure is to establish a process for the weighing and dispensing of powder and liquid raw materials.

## 2.0 Scope

This procedure applies to the weighing and dispensing of powder and liquid raw materials at Ion Labs, Inc.

## Responsibility

- 3.1 It is the responsibility of all personnel involved in the weighing and dispensing of powder and liquid raw materials to follow this procedure.
- 3.2 It is the responsibility of the Department Manager/Supervisor to implement this procedure and to ensure that all involved personnel are adequately trained.
- 3.3 It is the responsibility of QC to inspect and ensure that this procedure is followed.

## 4.0 Definitions

- 4.1 **Weighing** – The process of grouping appropriate amounts of necessary materials used in a specific stage of a manufacturing process
- 4.2 **Dispense At Site (DAS)** – The process of weighing / dispensing a specified quantity during the manufacturing operation rather than at the weighing / dispensing process
- 4.3 **BPR** – Batch Production Record

Standard Operating Procedure <b>Weighing and Dispensing Procedure</b>	<b>SOP No</b> <b>B-910</b>	<b>Rev No</b> <b>4</b>	<b>Page</b> <b>2 of 10</b>
--	-------------------------------	---------------------------	-------------------------------

- 4.4 **QC** – Quality Control
- 4.5 **R Number** – Receiving Number; a unique identifying number assigned to raw materials upon receipt
- 4.6 **RMID Number** – Raw Material Identification Number
- 4.7 **FIFO** – First In, First Out; an inventory plan that ensures that items purchased first will be used first. Raw materials, components, drug related products, containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.
- 4.8 **Issuance** – The process of identifying materials in inventory and selectively placing them as used in a batch
- 4.9 **ERP** – Enterprise Resource Planning
- 4.10 **PPE** – Personal Protective Equipment
- 4.11 **LPN** – License Plate Number; A unique identifier in for a given handling unit, commonly a pallet, that is used to track that handling unit throughout its lifecycle

## **5.0 References**

- 5.1 A-108, SOP, Good Manufacturing Practices and Personal Hygiene
- 5.2 QS-106, SOP, Allergen Control
- 5.3 A-107, SOP, Workplace Safety Procedure
- 5.4 F-510, SOP, Sharp Instrument Control Procedure
- 5.5 C-201, SOP, Deviation and Investigation Procedure
- 5.6 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

<b>Standard Operating Procedure</b> <b>Weighing and Dispensing Procedure</b>	<b>SOP No</b> <b>B-910</b>	<b>Rev No</b> <b>4</b>	<b>Page</b> <b>3 of 10</b>
---	-------------------------------	---------------------------	-------------------------------

- 5.7 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.8 B-901, SOP, Blending Procedure – Powders
- 5.9 B-908, SOP, Blending Procedure – Liquids
- 5.10 G-207, SOP, Calibration Verification and Operation of Scales
- 5.11 E-901, SOP, Shipping and Receiving Transport Inspection

## **6.0 Weigh Staging**

- 6.1 Before staging begins, generate and gather the following documents for the batch for the weighing/dispensing process.
  - 6.1.1 A picklist of the batch
  - 6.1.2 The batch record for the batch

**Note:** Materials must be picked and allocated in FIFO order unless justification can be provided.
- 6.2 Weighing personnel will confirm that all materials are in Released status or in an At Risk status.
- 6.3 Weighing personnel will designate and label an area with the batch number of the finished product and the stage they are staging.
- 6.4 Before moving any material into the weighing room, the operator and QC inspector must check the following on the raw material container:
  - 6.4.1 Check the material RMID number against the BPR.
  - 6.4.2 Check the description of material against the BPR, and the supplier container tag.
  - 6.4.3 Document the verification that the materials are accurate (RMID number, R

Standard Operating Procedure Weighing and Dispensing Procedure	SOP No B-910	Rev No 4	Page 4 of 10
---	-----------------	-------------	-----------------

number, and description of the material with a signature and date in the BPR from a weighing operator and QC).

**Note:** If the material description or RMID number does not match those listed in the BPR, contact QC and Production Management. QC will place a hold tag on the material in question and isolate it from the remaining raw materials. Do not proceed until QC or Production Management indicates that it is acceptable to proceed.

6.4.4 Check the R numbers and quantities outlined on the pick list provided against what is physically located inside the weighing room. This information must be consistent.

## 7.0 Weighing

### 7.1 General Requirements for Weighing rooms

7.1.1 Personnel and visitors must follow good manufacturing practices as per SOP A-108 Good Manufacturing Practices and Personal Hygiene. Personnel must follow safety precautions by wearing appropriate PPE as outlined in SOP A-107 Workplace Safety Procedure.

7.1.2 Personnel must wear company frocks and/or lab coats, hairnets, shoe covers and/or dedicated shoes (as applicable), beard covers (if applicable), dust masks, gloves, and safety glasses.

7.1.3 Operators must use stainless steel scoops or disposable scoops for the weighing of raw materials.

7.1.3.1 If using stainless steel scoops, the scoops must be cleaned between the weighing of raw materials and transported from the wash area to the weigh room in a clean and sanitized container or bag. Once returned to the weigh room, the scoops must be sanitized with IPA and allowed to dry prior to being used.

- 7.1.3.2 For materials containing an allergen, yellow scoops must be used. Allergen scoops shall be cleaned between the weighing of allergen materials and transported from the wash area to the weigh room in a clean and sanitized container or bag. Once returned to the weigh room, the scoops must be sanitized with IPA and allowed to dry prior to being used.
- 7.1.3.3 If using disposable scoops, the scoops must be discarded after each raw material type has been weighed. Disposable scoops cannot be used to weigh more than one type of raw material. It is acceptable to use the same scoop when weighing different lots of the same raw material.
- 7.1.4 When weighing materials that require cold storage pull the materials from the cooler only at the time of weighing and immediately place material back in cooler after weighing. Material weighed for the batch will need to be placed in a portable cooler for transportation and marked with a 'keep refrigerated sticker'. The items that require cold storage need to be specified by the weighing operator on the weigh and mix page in the batch record.
- 7.1.5 Operators must use approved blades to preform job duties as referenced in SOP F-510 Sharp Instrument Control Procedure.
- Note:** Gloves must be changed and discarded or sanitized after the weighing process of each raw material.
- 7.2 Complete room clearance before bringing any materials into the room by meeting the following requirements:
- 7.2.1 Ensure that the weighing room and utensils are clean and the cleaning has been properly documented as outlined in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.
- 7.2.2 Ensure that a daily scale performance check is complete and documented as outlined in SOP G-207 Calibration Verification and Operation of Scales.

- 7.2.3 Check the scale calibration sticker to ensure that the scale calibration has not expired. Report expired calibration to QC personnel. Do not use equipment with an expired calibration.
- 7.2.4 Check the calibration status of any other equipment required by the BPR. For example, if a hygrometer is required by the BPR to record humidity levels, ensure that the hygrometer calibration is not expired.
- 7.2.5 Identify the weighing room with the correct product detail tag.
- 7.2.6 Document the verification of room clearance with a signature/date in the BPR from a weighing operator and QC.
- 7.3 Allergen Controls
- 7.3.1 If allergenic materials are included for this stage of the batch, adhere to the items in the “Allergen Controls” section.
- 7.3.2 Remove all non-allergenic materials from the weighing room. This includes allergenic materials that are not in the same class as this allergenic material.
- 7.3.3 Ensure proper utensils are used and frocks/lab coats are worn during the handling/processing of any allergen materials as defined in SOP A-108 Good Manufacturing Practices and Personal Hygiene and QS-106 Allergen Control to eliminate any chance for cross contamination. Frocks and lab coats must be changed after allergen usage. Ensure a proper clean has been performed prior to the start of any weighing of raw materials containing allergens.
- 7.4 General Weighing Process
- 7.4.1 During the weighing process, the following steps should be observed:
- 7.4.1.1 Set the scale to the unit of measurement (kg or lb) indicated on the BPR.
- 7.4.1.2 Tare the scale to read zero between each weighing step.

- 7.4.1.3 Document the R number of each raw material in the BPR.
- 7.4.1.4 If multiple R numbers are used, document each R number and the individual weight in the amount section of the BPR.
- 7.4.1.5 All raw materials weighed shall be double bagged with the approved liners used for weighing.
- 7.4.1.6 Materials that are identified as environmentally unstable outside the original manufacturing container will need to be weighed out last and NMT 48hrs before the kitted batch is sent to production. Raw materials are identified as light and/or air sensitive on the raw material label that is affixed to the containers.
- Note:** Use FIFO during the weighing process if multiple R numbers are received from warehouse personnel.
- 7.4.1.7 The weighing operator will issue each individual lot of material from inventory in the ERP inventory system.
- 7.4.1.8 After weighing, the container/bag of material to be returned to inventory additionally needs to be weighed on the scale and amount verified before returning materials to the warehouse. The container/bag should be closed and sealed in a plastic bag (secondary confinement) and then removed from the room.
- 7.4.1.9 Returned material should be sealed with yellow tape and a yellow return tag.
- Note:** The color yellow signifies a partial container or container that the original quantity shown has now decreased and been decremented from.

## 8.0 Batch Building

- 8.1 Weighing personnel will designate and label an area with the batch number of the finished product and assemble weighed and counted materials for the batch into this area.
- 8.2 Weighing personnel will create an LPN sticker for each pallet containing the following information:
- 8.2.1 Finished product batch number the weighed batch is for
  - 8.2.2 Product manufacturing stage the batch is for (i.e. Powder blending, Liquid blending, coating)
  - 8.2.3 The pallet number in this batch
- 8.3 Weighing personnel will generate a manifest, summarizing the following information about the weighed materials:
- 8.3.1 Finished product batch number the weighed materials are for
  - 8.3.2 Product manufacturing stage the weighed materials are for (i.e. Powder blending, Liquid blending, coating)
  - 8.3.3 The total number of containers & weight
- 8.4 Warehouse management or weighing lead will verify the accuracy of the completed batch against the manifest generated and the BPR.
- 8.5 Weighing personnel will wrap each pallet to minimize the possibility of losing weighed components during transportation and storage.
- Note: Each pallet must be wrapped tightly and completely, from bottom to top, and labeled accordingly with a license plate.
- 8.6 Quality personnel will verify that completed weighed materials are suitable for transport

<b>Standard Operating Procedure Weighing and Dispensing Procedure</b>	<b>SOP No B-910</b>	<b>Rev No 4</b>	<b>Page 9 of 10</b>
---	-------------------------	---------------------	-------------------------

and that all documentation is in order.

- 8.7 A report of all materials issued to the batch will be printed and sent with the physical batch. Lot statuses and expiration dates are quality reviewed at this time.
- 8.8 Prior to transportation, the weighing lead and a quality personnel will perform a container count.
- 8.9 A completed batch will have the following documentation:
  - 8.9.1 A manifest
  - 8.9.2 A BPR
  - 8.9.3 LPN stickers on each pallet

## **9.0 Transportation and Storage of Completed Weighed Batches**

- 9.1 Completed weighed batches are stored in a Kanban lane along with the associated documentation generated and collected until time of transportation.
- 9.2 Completed weighed and tightly wrapped batches are transported to the production facility when the weighed batch is ready for blend.
- 9.3 Company trailers used to transport completed weighed batches will be inspected as outlined in SOP E-901 Shipping and Receiving Transport Inspection.
- 9.4 A trailer seal will be added to each shipment of completed weighed batches to ensure integrity of the batch during transportation to the production facility. The seal number will be documented during the incoming inspection of the trailer as it arrives at the production facility.
- 9.5 Prior to blend, blending lead or supervisor verify weighed out materials against the BPR and sign off on the verification step.

### 10.0 Revision History

Revision	Date	Description of Change	CCR #	By
0	09/30/22	New procedure	N/A	J. Murphy
1	06/15/23	Changed to disposable scoops. Expanded transportation requirements of completed weighed batches. Changed third material verification requirement to main facility blender responsibility. Added container count requirements.	CC-23-0202	J. Murphy
2	11/11/23	Added the option of stainless steel scoops. Added additional information for scoop control.	CC-23-0553	J. Murphy
3	02/18/25	Removed process for allocation approval.	CC-25-0076	J. Murphy
4	01/12/26	Weighed raw materials need to double bagged, environmentally unstable materials to be weighed out last	CC-26-0008	J. Murphy