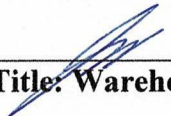
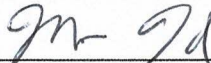
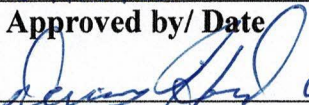
	Standard Operating Procedure Weighing and Blending Procedure - Liquids		SOP Number B-908	Revision 1
			Effective Date 09/18/23	Page Page 1 of 9
Written by/ Date  06/15/23		Reviewed by/ Date  07/26/23		Approved by/ Date  07-27-23
Title: Warehouse Manager		Title: Senior VP of Operations		Title: Quality Assurance Director

1.0 Purpose

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

2.0 Scope

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

Responsibility

- 3.1 It is the responsibility of all personnel involved in the weighing and blending of 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 being followed.

4.0 Definitions

- 4.1 **BPR** – Batch Production Record
- 4.2 **QC** – Quality Control
- 4.3 **R Number** - Receiving Number; a unique identifying number assigned to raw materials upon receipt
- 4.4 **RMID** – Raw Material Identification Number

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- 4.5 **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.
- 4.6 **Allocation** – The process of identifying materials in inventory and selectively placing them for use in a batch
- 4.7 **PPE** – Personal Protective Equipment
- 4.8 **PDT** – Product Detail Tag

5.0 References

- 5.1 C-707, SOP, Critical Control Point Specifications
- 5.2 A-108, SOP, Good Manufacturing Practices and Personal Hygiene
- 5.3 QS-106, SOP, Allergen Control
- 5.4 A-107, SOP, Workplace Safety Procedure
- 5.5 F-510, SOP, Sharp Instrument Control Procedure
- 5.6 C-201, SOP, Deviation and Investigation Procedure
- 5.7 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment
- 5.8 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.9 B-104, SOP, Floor Drain Cleaning and Sanitizing Procedure
- 5.10 C-707-F9, Form, CCP 6 – Liquid Tank Sampling

6.0 General Requirements

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- 6.1 Ensure that the liquid blending room, liquid tank, scoops, and pump are clean and that cleaning has been performed as per SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.
- 6.2 Ensure that the blending room is clear of all evidence of the prior batch, including the BPR, raw materials, and in-process materials.

Note: If needed, product may remain in the tank for holding. The tank must have proper observable signage.

- 6.3 Ensure that scale calibration is verified daily and that the designated logbook has been filled out.
- 6.4 Check the scale calibration sticker to ensure that the scale calibration has not expired. Report expired calibration to QC personnel. Do not use expired calibration equipment.
- 6.5 Identify the weighing/blending room with the correct product name and batch number.
- 6.6 A QC inspection of the room, equipment, balances, and utensil cleanliness must take place prior to bringing any raw materials into the room. The inspection must be documented in the BPR.
- 6.7 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.
 - 6.7.1 Personnel must be garbed appropriately with 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.
 - 6.7.2 Operators must use clean scoops and hoses between the weighing of different materials.

Note: Gloves must be changed and discarded (or sanitized) after the weighing process

of each raw material.

6.8 For raw materials containing allergens

6.8.1 Ensure that 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, as well as SOP QS-106 Allergen Control to eliminate any chance for cross-contamination.

6.8.2 Frocks and lab coats must be changed after allergen usage.

6.8.3 Ensure a proper clean has been performed prior to the start of any blending or weighing of raw materials containing allergens.

Note: Labeled stainless steel or yellow scoops will be utilized for allergen materials. All non-labeled stainless steel scoops will be utilized for non-allergen materials.

6.9 A material allocation report is required for every blend. This report must accurately reflect all raw materials that are intended for the batch and the expiration date of each material. If an R number is missing from the report, it must be added and approved for use individually by the QC Laboratory and/or Quality Assurance.

6.10 Before proceeding to the weighing process a final container count of raw materials against the BPR is performed.

6.11 For a batch that contains both liquid raw materials and powder raw materials the powder raw materials will be previously weighed following SOP B-910; liquid raw materials will be dispense on site.

6.12 During the weighing process, the following steps should be observed:

6.12.1 Set the scale to the unit of measurement (kg) indicated in the BPR.

6.12.2 Tare the scale to read zero between each weighing step.

6.12.3 The R number of each raw material must be documented in the BPR.

6.12.3.1 If multiple R numbers are used, document each R number and the individual weight in the amount section of the BPR.

Note: FIFO during the weighing process if multiple R numbers are received from warehouse personnel.

6.12.4 Each step of the weighing process must be checked by a second production employee prior to completing the item's full weigh-out to ensure that an accurate amount of the liquid is added to the tank.

6.12.5 After the weighing process has been completed, all material containers must be closed and sealed. Plastic or paper bags should have secondary confinement before being removed from the room.

6.13 During the blending process, the following steps should be observed:

6.13.1 Place the weighed raw materials into the liquid tank, following the instructions as outlined in the BPR.

6.13.2 Each step of the blending process must be checked by a second production employee.

7.0 Procedure

7.1 Retrieve the batch record (to confirm what manufacturing room will be used) and allocation sheet.

7.2 Ensure that cleaning has been performed and documented properly AND approved by QC prior to bringing any materials into the room.

7.3 Place a PDT on the door of the blending room and liquid tank.

7.4 Bring the raw materials staged by the warehouse into the liquid blending room. Ensure that the raw materials match the BPR.

Note: All product holding drums must be wiped down with IPA on the outside of the drum and the lid to remove excess powder prior to removing from the blending and compression areas.

7.5 Review the BPR to ensure that all steps are correct and all items are accounted for. Also review what equipment is needed for the batch.

7.6 Gather all necessary supplies. At a minimum, the following supplies will be needed:

7.6.1 Hygrometer

7.6.1.1 Ensure that the hygrometer calibration has not expired.

7.6.2 Tape gun

7.6.3 Scoop

7.6.4 Marker

7.6.5 Pen

7.6.6 Zip ties

7.6.7 Return labels

7.6.8 Box cutter

7.6.8.1 Follow SOP F-510 Sharp Instrument Control Procedure for proper assignment and maintenance of blades.

7.6.9 Scissors

7.6.10 Bags

7.6.11 Snips

7.6.12 Weigh-out containers

7.6.13 Scale(s)

7.6.13.1 Ensure that the scale calibration has not expired. Following SOP G-207 Calibration Verification and Operation of Scales, verify the calibration and document in the calibration log book.

- 7.7 Separate all material, first by ID number and then by R number to ensure a streamlined inspection of materials.
- 7.8 Complete all batch documentation for room/equipment verification checklist and raw material assignment. R numbers are to be added to the weigh-out sheet in FIFO.
- 7.9 When all of the above steps are complete, call QC to verify the raw materials and documentation.
- 7.10 Fill in the start time on the blending instruction page and start weighing out the raw materials. Label all materials by item number, weight, and R number on partial containers, and item number on full containers for the powder part.
- 7.11 Stage all raw materials for any premixes that are required per the blending instructions (hand screen or liquid tank mixes). Once staged the premixes may be completed.
- 7.12 Stage the remaining raw materials for addition to the liquid tank. All liquid raw materials must be fully checked prior to full addition to the tank.
- 7.13 Follow the blend instructions exactly as outlined in the BPR. Deviations to the instructions as outlined (except for additional material screening) must be managed through deviation. Refer to SOP C-201 Deviation and Investigation Procedure.
- 7.14 While the blend is in-process, prepare a bottle for CCP 6 Liquid Tank Sampling.
- 7.15 Equip the discharge valve with either a 12-mesh or 10-mesh screen to dispense liquid to the next step of the production process. If the blend flows freely through the screen and no clumps are noted, change to 4-mesh screen and discharge the remainder of the blend into the prepped containers. Wrap the top of the liner and close the container with a

tight-fitting lid.

Note: Wrap/cover the blending tank when the blend is complete.

7.16 Calculate the net weight of each container using the following calculation:

7.16.1 Gross Weight – Tare Weight = Net Weight

7.17 Once the weight of all items has been calculated and the samples have been subtracted, enter the weight on the BPR Weigh and Mix sheet. Record the liquid weight on the container for the associated line.

7.18 Use the subtracted number of samples to fill in for waste on the waste column. This number will be documented on the Blending Master Reconciliation page, in the Transfer Out column. The numbers must be confirmed by a second blending operator (or equivalent).

7.19 Complete all required calculations on the Master Blending Reconciliation and have a second blender confirm these calculations. Once confirmed, the blending section of the BPR can be closed. Notify QC Lab to perform CCP 6 Liquid Tank Sampling to ensure blend uniformity, to determine that the blend conforms to specifications, and to make a disposition decision. Refer to SOP C-707 Critical Control Point Specifications.

7.19.1 Once CCP 6 has been approved by the QC Lab, blending personnel will move the drums into the blending release area.

7.19.2 QC will label the drums that fail with a hold sticker and move the drums into the QC Hold area to await a disposition decision.

Note: All product holding drums must be wiped down with IPA on the outside of the drum and the lid to remove excess powder prior to removing from the blending and compression areas.

7.20 After blending, cleaning of the blending room and equipment should be performed and properly documented according to the appropriate cleaning and equipment SOPs.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	08/11/21	New procedure.	N/A	D. Pitman
1	06/15/23	Updated procedure throughout to clarify process. Updated logo and format.	CC-22-0221	J. Murphy