

	Standard Operating Procedure		SOP Number B-312	Revision 4
	V-Blenders		Effective Date 06 Y1 10	Page Page 1 of 4
Written By/Date <i>TS-MJ. 11/2/20</i>	Reviewed By/Date <i>D. Z. T. 11/4/20</i>	Approved By/Date <i>[Signature] 06/12/20</i>		
Title: EH&S Manager	Title: Blending Supervisor	Title: QAM/raeger		

1.0 Purpose

This procedure defines the process for the setup, operation, and cleaning of the 6, 40, 50, and 100 cubic foot v-blenders.

2.0 Scope

This procedure applies to the 6, 40, 50, and 100 cubic foot v-blenders in operation at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all production (blending) personnel to follow this procedure.
- 3.2 It is the responsibility of the department supervisor/manager to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of all operators to immediately report any equipment which is malfunctioning or not working to the department supervisor.
- 3.4 It is the responsibility of all department Supervisors to immediately report any equipment malfunctioning, not working, or any safety concern to the EHS Manager, Maintenance and the Facilities Manager for an operational disposition.
- 3.5 It is the responsibility of the supervisor to create a work order, clearly and specifically document the level of priority and ensure a system generated Work Order has been successfully entered by obtaining a copy of the work order with a computer generated number specific to that work order.
- 3.6 It is the responsibility of the Maintenance Manager and/or the Facility Manager to ensure all work orders are processed quickly, accurately and fully.
- 3.7 It is the responsibility of the Maintenance Manager and/or the Facility Manager to immediately and completely repair and render safe all reported malfunctioning or not working equipment.
- 3.8 The Maintenance Manager and/or Facility Manager must communicate the status of all high priority repairs to all affected department Heads.

4.0 Definitions

- 4.1 IPA = 70% Isopropyl Alcohol
- 4.2 BPR = Batch Production Record
- 4.3 QC = Quality Control

5.0 References

- 5.1 B-103, SOP, Small Parts Cleaning and General Sanitation

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

5.3 SOP G-104 Lockout Tag out Procedure

5.4 SOP G-105 Lockout Tag out Devices

6.0 Procedure

6.1 Setup

6.1.1 Inspect and verify that the room and equipment have been properly cleaned and the cleaning log has been signed from the previous batch by a QC inspector.

6.1.2 Obtain the BPR from the QC area. Using the BPR, enter the product name and batch number in the cleaning logbooks.

6.1.3 Initial and date all entries. Call a QC inspector for approval.

6.2 Operation

Note: The 6cu v-blender and 40cu v-blender have intensifier bars that will be used as specified in the BPR. Refer to the weigh and mix order for instructions on intensifier bar usage.

6.2.1 Bring the previously weighed, screened, or milled raw materials into the room.

6.2.2 Use the drum lifter, ladder, Vac U Max or manually load the raw materials into the blender, following the order specified in the BPR.

6.2.2.1 Before loading the raw material into the blender located in Blending Room B-2, mount and secure the stainless steel food grade funnel between the mezzanine rail and the blender opening.

6.2.2.2 Pour the raw materials into the blender using the funnel.

6.2.2.3 Never step over railing onto blender frame. Breaching the platform and/or the safety railing for any reason will result in discipline up to termination.

6.2.2.4 In the event the drum lift or elevator is inoperable for any reason, this must be reported immediately.

6.2.2.4.1 Immediately Lock out and Tag out per SOP G-104 and G-105 any drum lift or elevator which is not operating properly.

6.2.2.4.2 A forklift may be used to lift the raw materials to the platform level for loading into the blender.

6.2.2.4.3 When in Blending room 2 use the funnel attachment to pour raw materials into blender.

6.2.3 When all raw materials have been properly loaded into the blender, secure the lids.

Note: Prior to the "ON" and "OFF" operation of the blender, the operator(s) must attach the safety barricade that will not allow operator entrance past the yellow caution marking identified on the floor while the equipment is

in operation.

Note: All associates must adhere to the safety barricade, caution markings, and door cautions while equipment is in operation.

6.244 Turn the power box to the ON position.

6.255 Lift the lever on the power box to the ON position.

6.266 Set the timer for the blender for the time specified in the BPR or protocol.

6.3 Discharging the Blender

6.311 Pull down the lever on the power box to the OFF position.

6.322 Prepare the proper number of clean containers.

6.333 Line the containers with clean plastic bags.

6.344 Place the prepared container under the outlet valve. Secure the plastic bag around the outlet valve.

6.355 Open the outlet valve and fill the container.

6.366 When the container is full, close the outlet valve.

6.377 Close the bag by placing a seal on the bag.

6.388 Prepare an in-process label and secure it to the outside of the container.

6.399 Repeat steps 6.3.3 through 6.3.8 until the blend has been completely discharged.

6.3.100 If excess powder is present in the blender, scoop it out and place it into a container.

6.4 Cleaning

6.411 Remove all materials and paperwork from the previous batch.

6.422 Follow SOPs B-103 Small Parts Cleaning and General Sanitation and B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning procedure applicable to this type of equipment.

6.5 When cleaning the ground floor of the elevators the Supervisor only must take these steps to render the elevator safe:

6.511 The Supervisor must raise the elevator to the top floor and engage the E-stop button rendering it locked in place.

6.522 The Supervisor must isolate and render the disconnect inoperable by dropping the handle to off and Lockout the disconnect.

6.533 The Supervisor must then manually release the door magnet allowing door to open and the ground floor to be cleaned.

6.544 When the cleaning complete and quality has signed off, the Supervisor must ensure the elevator is completely clear, close the door engaging the magnet, activate the Start button, remove the lock from the power source, and raise the handle re-energizing the equipment.

666 Only after all of these steps are taken by the Supervisor, may operators continue to use the elevators in any room.

666.1 Document cleaning in the cleaning logbook.

666.2 Contact a QC inspector to verify equipment and room cleanliness and check the cleaning logbook.

7.00 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/28/14	New	14-0472	S. Kovalik
1	03/30/15	Added notes in section 6.2.3.	15-0297	K. Burris
2	06/23/15	Revised to include all v-blenders.	15-0549	E. Cummings
3	01/08/19	Scheduled review: removed obsolete definitions. Added reference to SOP B-111 and B-103. Revised section 6.4.	19-0029	K. Burris
4	05/20/20	Safety Guidelines and use offunnel added	CC-20-0861	K. Patton