

	Standard Operating Procedure		SOP Number B-621	Revision 5
	Powder Fillers		Effective Date 10/16/23	Page Page 1 of 6
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1.0 Purpose

The purpose of this procedure is to define the process for the setup, operation, and cleaning of powder fillers.

2.0 Scope

This procedure applies to any powder filler in operation at Ion Nutritional Labs.

3.0 Responsibility

- 3.1 It is the responsibility of Production (Packaging) personnel to follow this procedure.
- 3.2 It is the responsibility of Production Management to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of Production Management and/or Maintenance & Engineering personnel to keep this procedure aligned with current practices.

4.0 Definitions

- 4.1 **QC** – Quality Control
- 4.2 **FF** – Free Flow
- 4.3 **Non-FF** – Non-Free Flow

5.0 References

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

5.2 B-105, SOP, Preparation of Cleaning and Sanitizing Chemicals for Production

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

6.0 Procedure

6.1 Setup

Note: Refer to the machine manual for setup and operation.

Note: Ensure that the machine is clean, sanitized, and cleared of all previously used materials.

6.1.1 Dual-head Filler

6.1.1.1 Ensure that the indexing pins are set up correctly so that the selected bottle can be consistently spaced.

6.1.1.2 Determine the conveyor speed required and adjust guides as needed.

6.1.1.3 Determine and install the Hopper Assembly required, based on the selected product powder:

6.1.1.3.1 Install Auger Shaft.

6.1.1.3.2 Install Agitation Blade.

6.1.1.3.3 Install High-Speed "D" Agitation Blade.

6.1.1.3.4 Install correct Auger (FF/non-FF, size).

6.1.1.3.5 Install Hopper(s).

6.1.1.3.6 Install correct Funnel (Straight, Lip, etc.).

6.1.1.3.7 (ONLY for FF Auger) Install Spinner Plate.

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6.1.1.3.8 (ONLY for FF Auger) Install Collector Funnel.

6.1.1.3.9 Connect hopper to product dispense tube.

6.1.1.4 Power on the AMS Filler.

6.1.2 Rotary Filler

6.1.2.1 Install and adjust the timing screw for the product being run.

6.1.2.2 Determine the conveyor speed required and adjust guides as needed.

6.1.2.3 Determine and install the Hopper Assembly required, based on the selected product powder:

6.1.2.3.1 Install Dust Shroud.

6.1.2.3.2 Install Shroud Vents.

6.1.2.3.3 Install Track Base.

6.1.2.3.4 Install Intake and Discharge Star Wheels.

6.1.2.3.5 Install Center Star Wheel.

6.1.2.3.6 Install Center Track pieces.

6.1.2.3.7 Install Rubber Flex Seals.

6.1.2.3.8 Install Auger Shaft.

6.1.2.3.9 Install Agitation Blade.

6.1.2.3.10 Install High-Speed "D" Agitation Blade.

6.1.2.3.11 Install correct Auger (FF/non-FF, size).

6.1.2.3.12 Install Hopper.

6.1.2.3.13 Install correct Funnel (Straight, Lip, etc.).

6.1.2.3.14 (ONLY for FF Auger) Install Spinner Plate.

6.1.2.3.15 Install Collector Funnel.

6.1.2.3.16 Install Yoke Connector.

6.1.2.3.17 Install Hopper Vent.

6.1.2.3.18 Install Air Vacuum.

6.1.2.4 Power on the AMS Filler.

6.2 Operation

6.2.1 Ready up the AMS Filler.

6.2.2 Fill the hopper with product.

6.2.3 Adjust the Machine Settings based on the product being run.

6.2.3.1 The Machine Settings must be observed during the entire packaging run and adjusted based on the following metrics.

6.2.3.1.1 Number of bottles filled per minute

6.2.3.1.2 Fill amount required

6.2.3.1.3 Conveyor speed

6.2.3.1.4 Auger Revolution setting

6.2.3.1.5 Vibration setting

6.2.3.1.6 Agitation setting

6.2.3.2 The Machine Settings are performing as required when the following occurs:

6.2.3.2.1 The bottle is consistently filled with the amount of product required.

6.2.4 Monitor and adjust the following systems as needed:

6.2.4.1 Indexing Assembly/Timing Screw

6.2.4.2 Conveyor Setup

6.2.4.3 Hopper Assembly

6.2.4.4 Machine Settings

6.3 Cleaning

6.3.1 Prepare cleaning agents as outlined in SOP B-105 Preparation of Cleaning and Sanitizing Chemicals for Production.

6.3.2 Follow SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to ensure proper cleaning and sanitization are performed for this type of equipment and that these activities are properly documented.

6.3.3 Refer to SOP B-103 Small Parts Cleaning and General Sanitation to follow appropriate cleaning steps for small parts.

6.3.4 For required disassembly of this equipment, work backwards from the applicable steps in section 6.1.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	09/02/10	New	-	-
1	05/03/13	Updated SOP format.	13-297	B. Mosall
2	09/04/14	Added not for allergen materials. Updated SOP format.	14-0688	K. Burris
3	9/02/16	Biennial review: Corrected numbers in step 6.4.8. Revised equipment identification after minor and major cleaning.	16-0801	K. Burris
4	09/11/19	Scheduled review: Removed obsolete definitions. Added reference to SOP B-111 and SOP B-103.	19-0651	K. Burris
5	09/19/23	Scheduled review: Revised section 6. Included new definitions and changed SOP title.	CC-23-0476	A. Gatev