



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of Dusting Powder Filling Machine	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Dusting Powder filling machine.

2.0 SCOPE:

This SOP is applicable during Operation & Cleaning of Dusting Powder filling machine.

3.0 RESPONSIBILITY:

Operating Person- Production.

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR Batch Production and Control Record
HDPE High Density Poly Ethylene
QA Quality Assurance
QC Quality Control
SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 Operation:

6.1.1 Before starting the machine check & ensure that area and machine are clean. Take the line clearance from QA as per "Line clearance" SOP and enter the details in BPCR and Equipment log.

6.1.2 Ensure the temperature and humidity of area within limits as specified in BPCR.

6.1.3 Affix the status label on the machine.

6.2 Setting of machine:

6.2.1 Switch 'ON' the main supply.

6.2.2 Charge the dusting powder in the hopper through S.S Scoop.

6.2.3 Turn the stirrer knob to 'ON' position by manual mode.

6.2.4 Turn the feeder knob to 'ON' position when filling of powder starts in the Auger chamber.



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- 6.2.5 Place the cleaned HDPE bottle on the conveyor belt and switch on the conveyor belt.
- 6.2.6 Turn the bottle sensor knob to 'ON' position.
- 6.2.7 Turn the star wheel to 'ON' position.
- 6.2.8 Weight adjustment of powder in the HDPE bottle:
- 6.2.9 Press the count key on PLC, and set the timer and RPM of the augur to adjust the weight.
- 6.2.10 Place an empty bottle under the dosing nozzle & weigh the fill content.
- 6.2.11 Set to increase or decrease the fill content as per specified in BPCR by Pressing the ^ (Up key) & v (Down key) on PLC if required.
- 6.2.12 Verify the set weight of the dusting powder and record the set weight in respective BPCR and start the powder filling operation after approval from QA.
- 6.2.13 After completion of process switch 'OFF' the machine and mains and Affix a label as "To be Clean" on the machine.
- 6.2.14 Enter the operation details in "Equipment log book"

6.3 Cleaning:

- 6.3.1 Cleaning to be done for Batch changeover of the same product and Product changeover is categorized in two different terminology i.e. Cleaning procedure for Batch changeover of the same product is refer as "Type A" cleaning. Type A to be done for lower strength to higher strength. Hold time for Type A cleaning is 48 hrs.
- 6.3.2 Cleaning procedure for Product changeover of the different product means it differs from the previous product is refer as "Type B" cleaning. Type B cleaning to be done After 5 batches of the same product or after 48hrs of Type A cleaning or from higher strength to lower strength or Machine is idle then type B cleaning to be done before starting of the operation or after any breakdown type B cleaning to be done.
- 6.3.3 **For Batch Changeover (Type A Cleaning):**
 - 6.3.3.1 Once the batch is completed kindly ensure the previous batch traces remove from the machine hopper and area.
 - 6.3.3.2 Mope the machine hopper from inside with dry lint free cloth, and from outside with wet lint free cloth using 70% IPA.



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6.3.3.3 Affix status label defining as “Cleaned” on the machine. Enter the cleaning details in “equipment log book”.

6.3.4 For product change over (Type “B” Cleaning):

6.3.4.1 Dismantle the machine product contact parts Hopper , augur and filling nozzle in poly bag as per Annexure-1 and put the status of “ TO be cleaned” and shift to washing area for cleaning.

6.3.4.2 Freshly prepared 2% Extran solution in SS container and dismantled part shall be dip in solution.

6.3.4.3 Mop the dismantled machine parts by manual scrubbing using nylon brush /muslin cloth from inside and outside properly to clear the traces of sticky material from the surface.

6.3.4.4 Rinse the dismantle machine part with hot purified water by jet flushing, till the rinse is free from foam.

6.3.4.5 Dry the dismantled machine parts by compressed air to remove the traces of the water from the machine surface.

6.3.4.6 After cleaning, the clean change parts shall be transferred to the powder filling area enclosed in poly bag on clean trolley (Ensure the cleanliness of the area and machine before shifting the clean change parts in the area).

6.3.4.7 After ensuring visual cleaning the officer QA Collect rinse/swab sample with rinse/swab test intimation to QC for analysis from assembled machine.

6.3.4.8 Start the operation after receiving rinse/swab test intimation slip cum analysis report from QC showing negative identification.

6.3.4.9 Investigation needs to be done for the reason of failure and re-cleaning to be done.

6.3.4.10 Mop the machine with wet lint free cloth by using 70% IPA and Affix a label as “Cleaned” on the machine.

6.3.4.11 Enter the cleaning details in “Equipment log book”

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Pictorial Display of Powder Filling Machine Product Contact Parts	



PHARMA DEVILS

PRODUCTION DEPARTMENT

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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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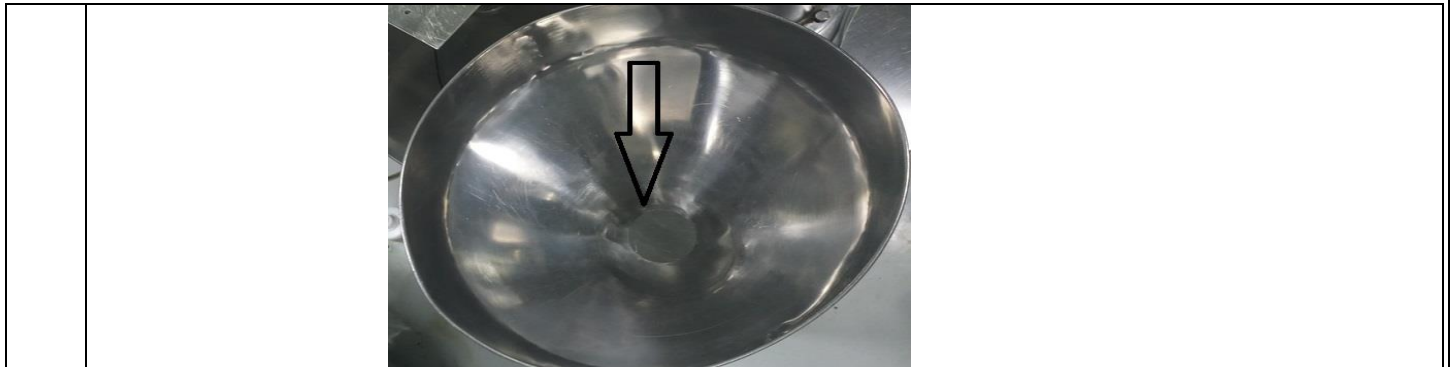
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ANNEXURE I

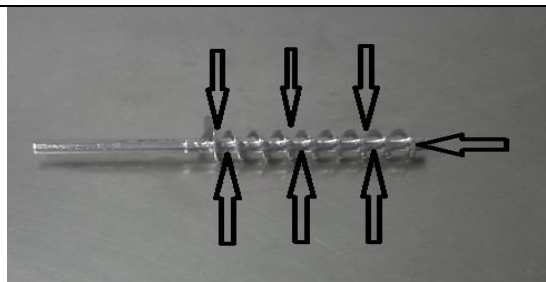
PICTORIAL DISPLAY OF POWDER FILLING MACHINE PRODUCT CONTACT PARTS



1. Hopper



2. Hopper cover



3. Auger



4. Bottle guide assembly



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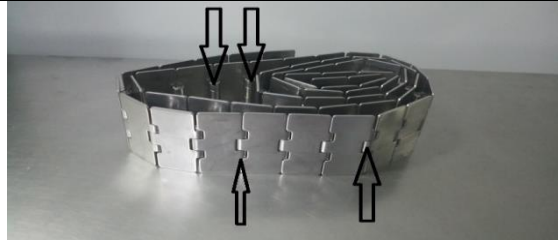
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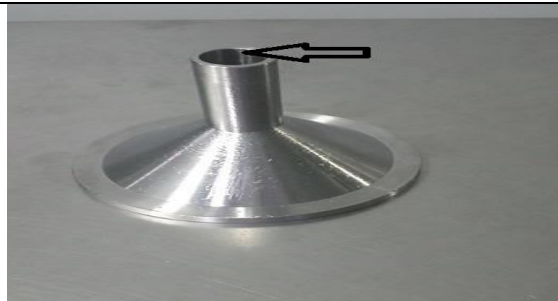
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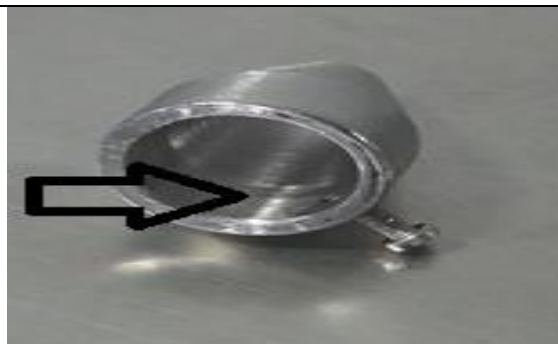
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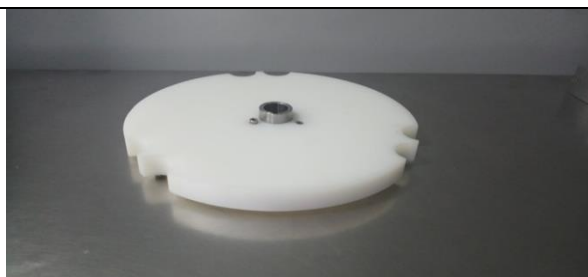
5. Chain Conveyor



6. Discharge cup



7. Discharge Chute



8. Star Wheel



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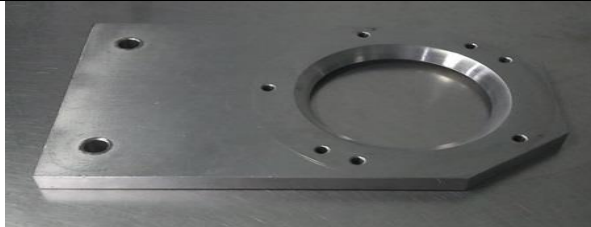
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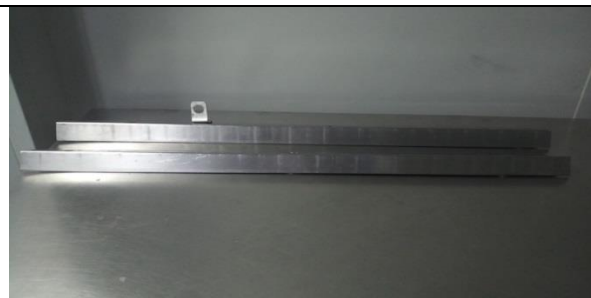
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9. Hopper base plate



10. Scrapper rods



11. Side Guards