



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of two Head Volumetric 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 Two Head Volumetric Filling Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Two Head Volumetric Filling Machine in Ointment section.

3.0 RESPONSIBILITY:

Production Officer/Executive

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
IPQA	In-Process Quality Assurance
PO	Production Ointment
No.	Number
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 GENERAL REQUIREMENT:

- 6.1.1 Hand gloves, nose mask and boiler suit.
- 6.1.2 Check all the machine functions and movements are working correctly.
- 6.1.3 Run the machine using the 'START' and 'STOP' buttons to check that the machine functions are operation correctly.
- 6.1.4 Check that the start and stop functions.
- 6.1.5 Check the cleanliness of Two Head Volumetric Filling Machine.
- 6.1.6 Check the "CLEANED" Status label on Two Head Volumetric Filling Machine.
- 6.1.7 Ensure that the Environmental Conditions are as per specification in BPCR and enter the same into BPCR as well as in Environmental Monitoring Record.
- 6.1.8 Remove the "CLEANED" status label from Equipment and place equipment "STATUS" label on it.

6.2 OPEARATION:

- 6.2.1 Connect the both pipes and nozzle with filling machine.
- 6.2.2 Transfer the BULK in to holding tank through transfer pump.
- 6.2.3 Switch on the machine (Main Switch).
- 6.2.4 Open the drain valve of holding tank which are connected from filling machine.



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6.2.5 Press the start button of filling machine for come out the bulk in to nozzle.

6.2.6 Set the fill volume by checking through measuring cylinder & with weight /ml as per pack size.

6.2.7 After set the fill volume than run the filling machine.

6.2.8 Make an entry of Operation Time in Equipment Log.

6.3 CLEANING:

6.3.1 A Type Cleaning (Batch to Batch)

6.3.1.1 Ensure that the equipment has a “TO BE CLEANED” status label.

6.3.1.2 Remove all residue of previous product.

6.3.1.3 Wash with Hot Purified Water Using Jet Pressure and dry with Compressed Air.

6.3.1.4 Dry mop the Dismantle parts and Filling Machine with lint free cloth.

6.3.1.5 Collect the cleaned & dry parts to the Filling Area and assemble them.

6.3.1.6 Affix a “CLEANED” status label on the Filling Machine.

6.3.1.7 Make an entry of Cleaning Time in Equipment Log in **Reference SOP**.

6.3.1.8 A - Type Cleaning is to be done.

1. Batch to Batch changeover of the same product.
2. Change over to higher strength of same color.
3. After every 5 batches of same product in case of campaign product should apply Type B Cleaning.

6.3.2 B-Type Cleaning (Product to Product Cleaning)

6.3.2.1 Ensure that the Equipment has a “TO BE CLEANED” Status label on it.

6.3.2.2 Clean the parts with Hot Purified Water Using Jet Pressure and dry with Compressed Air.

6.3.2.3 Re-wash the Dismantle parts with Hot Purified Water Using Jet Pressure and re-dry with Compressed Air.

6.3.2.4 Clean Filling Machine in filling Area with Hot Purified Water and dry with Compressed Air

6.3.2.5 Sanitized dismantle Part and Machine with 70% v/v IPA solution (If required).

6.3.2.6 Collect the cleaned & dry parts to the Filling Area and assemble them.

6.3.2.7 Ensure the cleanliness of Filling Machine visually.



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6.3.2.8 Affix a “CLEANED” Status label on the Filling Machine.

6.3.2.9 Make an entry of Cleaning Time in Equipment Log in **Reference SOP**.

6.3.2.10 B-Type Cleaning is to be done.

1. After 48 hrs of type A-Type cleaning.
2. Product Change Over.
3. Change over to Lower strength of same product.
4. After maintenance or major breakdown.
5. Change over to upper strength with different color.

** If the Equipment is not used within 5 days clean the equipment before use.

**After every 5 batches of same product in case of campaign product.

6.3.2.11 Send the Rinse Sample to Quality Control Department for chemical testing.

6.3.2.12 If Testing Results not complies with Reference Specification, again clean the All Dismantle parts of filling machine of Hot Purified water or till satisfactory & send the Rinse sample Quality control Department.

7.0 ANNEXURES:

Not Applicable.

ENCLOSURE: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Party Manuals

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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