



STANDARD OPERATING PROCEDURE

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

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Six 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
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 compressed air line Connection.
- 6.1.3 Check all the machine functions and movements are working correctly by driving the machine via the hand wheel.
- 6.1.4 Run the machine using the 'START' and 'STOP' buttons to check that the machine functions are Operation correctly.
- 6.1.5 Check the cleanliness of Six Head Volumetric Filling Machine.
- 6.1.6 Check the “CLEANED” Status label on Six 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 of area temperature and RH Record.
- 6.1.8 Remove the “CLEANED” status label from equipment and place equipment “INPROCESS STATUS” label on it.

6.2 OPEARATION:



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- 6.2.1 Connect all the six or four pipes and nozzle with filling machine as per production requirement.
- 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 bottom valve of holding tank which are connected from filling machine.
- 6.2.5 Press the start button of filling machine for come out the bulk in to nozzle.
- 6.2.6 Adjust the fill volume by checking through measuring cylinder as per pack size.
- 6.2.7 After adjust the fill volume then run the filling machine.
- 6.2.8 Make an entry of Operation Time in Equipment Log.

6.3 CLEANING:

6.3.1 Type-A 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 with purified water.
- 6.3.1.3 Wash with Hot Purified Water Using Jet Pressure and dry with filtered 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 **Type – A Cleaning has to be done.**
 - 6.3.1.8.1 Batch to Batch changeover of the same product.
 - 6.3.1.8.2 Change over to higher strength of same color.
 - 6.3.1.8.3 After every 5 batches of same product in case of campaign product should apply Type-B Cleaning.

6.3.2 Type – B Cleaning (Product to Product):

- 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 & elaborate for removal of Extran MA 02 solution 2% v/v.



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6.3.2.3 Wash the Dismantle parts with Hot Purified Water Using Jet Pressure and dry with Filtered Compressed Air.

6.3.2.4 Sanitized dismantle Part and Machine with 70% v/v IPA solution.

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

6.3.2.6 Ensure the cleanliness of Filling Machine visually.

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

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

6.3.2.9 Type - B Cleaning has to be done.

6.3.2.9.1 After 48 hrs. of Type-A cleaning.

6.3.2.9.2 After Product Change Over.

6.3.2.9.3 Change over to Lower strength of same product.

6.3.2.9.4 After maintenance or major breakdown of bulk contact parts.

6.3.2.9.5 Change over to upper strength with different color.

6.3.2.9.5.1 If the Equipment is not used within 72 hrs. clean the equipment before use.

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

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

6.3.2.9.7 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.

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



PHARMA DEVILS

PRODUCTION DEPARTMENT

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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