



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Automatic forming, filling and sealing machine.

2.0 SCOPE:

This procedure is applicable to Cleaning and Operation of Automatic forming, filling and sealing machine in Tablet Production Department.

3.0 RESPONSIBILITY:

Technical Associate: Operation

Officer/ Executive Production/IPQA: Supervision

Head Production: SOP Compliance.

4.0 DEFINITION(S):

NA

5.0 CLEANING PROCEDURE:

5.1 TYPE A CLEANING:

This is a cleaning procedure for change over of one batch to next batch of same product and same potency and of similar product with ascending potency.

5.1.1 Ensure that the Automatic forming, filling and sealing machine is switched OFF.

5.1.2 Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and signature of production officer.

5.1.3 Dry clean the Automatic forming, filling and sealing machine body, control panel and utility cables using a dry lint free cloth.

5.1.4 Remove the rotating disc from the machine and clean with clean dry lint free cloth. Remove the dosing cup from the rotating disc and clean with clean dry lint free cloth.

5.1.5 Clean the hopper of the machine with clean dry lint free cloth. Remove the collar from the machine and clean with clean dry lint free cloth.

5.1.6 Clean the vertical sealing roller and horizontal sealing plate with brass brush to remove all the adhered material.

5.1.7 Assemble the dismantled parts of the Automatic forming, filling and sealing machine.

5.1.8 Replace "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer.



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5.1.9 If the same product is processed for more than one week, then follow procedure of cleaning during product change over.

5.1.10 Record the cleaning activity in equipment usage log book as per SOP.

5.2 TYPE B CLEANING

This is a cleaning procedure for change over of product with different actives/colour/descending potency/after maintenance cleaning of contact parts.

5.2.1 Ensure that the Automatic forming, filling and sealing machines switched OFF.

5.2.2 Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and signature of production officer.

5.2.3 Dry clean the Automatic forming, filling and sealing machine body, control panel and utility cables using a dry lint free cloth.

5.2.4 Dismantle the hopper, rotating disc, dosing cup and Collar from the machine and clean with clean dry lint free cloth. Put all the parts in a virgin polybag and transfer to washing area.

5.2.5 Scrub all the above parts with nylon scrubber dipped in purified water and finally rinse all the parts with sufficient quantity of Purified water to remove any adhered material.

5.2.6 Finally rinse all the cleaned parts with the 40-50 liters of purified water.

5.2.7 Dry all the parts with compressed air followed by dry lint free cloth. Wipe all the parts with 70% v/v IPA Solution. Put all the cleaned parts in a virgin poly bag and transfer them to the designated area.

5.2.8 Clean the vertical sealing roller and horizontal sealing plate with brass brush by applying silica compound followed by dry lint free cloth to remove all the adhered material.

5.2.9 Clean the inner and outer surface of machine body, control panel, with wet lint free cloth followed by dry lint free cloth.

5.2.10 Replace "TO BE CLEANED" status label with "CLEANED" Status label with date and signature of the Production Officer and QA officer.

5.2.11 If the machine is idle for 72 hours after cleaning, then Re-clean by mopping with 70% v/v IPA solution with the help of a lint free cloth before use.

5.2.12 Again check on the previous 'CLEANED' status label by the Production Officer and QA Officer.

5.2.13 Record the cleaning activity in equipment usage log book as per SOP.

5.3 Frequency:

5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product, same potency and of similar product with ascending potency. If same product is processed for more than a week then follow the procedure of type – B cleaning.



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5.3.2 Type 'B' cleaning is applicable in case of change over of product with different actives / colour / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type - B done after completion of batch.

5.3.3 Cleaning is applicable in case of at the end of working day, dedusting of machine with vacuum cleaner or dry by lint free cloth.

NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the machine "before use", with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP.

5.4 OPERATING PROCEDURE

5.4.1 Replace the "CLEANED" status label with "UNDER PROCESS" status label with date and signature of production officer.

5.4.2 Switch "ON" the mains from electrical panel.

5.4.3 Mount the hopper, rotating disc to the Automatic forming, filling and sealing machine.

5.4.4 Affix the Collar and dosing cup in rotating disc for the specified product to the Automatic forming, filling and sealing machine.

5.4.5 Adjust the alignment of the vertical roller as per collar and foil dimension so the foil mounted on the shaft should move freely.

5.4.6 Check the vertical Knurling by adjusting the movement of the sealing roller with the help of bolts provided to tighten the sealing roller.

5.4.7 Length of the pouch is adjusted by changing the cutting gear of specific size. .

5.4.8 Check the horizontal Knurling by adjusting the movement of the sealing Plate with the help of bolts provided to tighten the sealing Plate, responsible for horizontal knurling.

5.5 Weight Adjustment:

5.5.1 Select the disc and dosing cup according to weight required by lifting up and down position to weight controlling plate.

5.6 Setting of coding unit.

5.6.1 Set the batch no. mfg. Exp. And other batch detail on batch code roller by metal stereo.

5.6.2 Adjust the printing by help of display unite.

5.6.3 Set the heating of cartridge by pressing 1 shown by display.

5.6.4 Set the distance between prints by pressing 2 shown by display.



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5.7 'I' mark setting

5.7.1 Control I mark with the help of photo electric control.

5.7.2 Adjust the cutting of I mark by controlling forward and reverse button fitted on photoelectric control.

6.0 ABBREVIATION (S):

SOP: Standard Operating Procedure.

No. : Number

7.0 REFERENCE(S):

SOP: Status labeling

SOP: Making entries in equipment usage and cleaning log sheet

8.0 ANNEXURE (S):

ANNEXURE I- Cleaning checklist of automatic forming, filling and sealing machine

9.0 DISTRIBUTION:

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department, Quality Assurance

9.3 **Reference copy (s)** : Production department



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ANNEXURE I

Cleaning checklist of automatic forming, filling and sealing machine

Name of the Equipment		AUTOMATIC FORMING, FILLING AND SEALING MACHINE	
Equipment ID No.		Previous product	
Batch No.		Date	
S.No.	Activity	Activity Performed	
1	Ensure that the Automatic forming, filling and sealing machines switched OFF.		
2	Dry clean the Automatic forming, filling and sealing machine body, control panel and utility cables using a dry lint free cloth.		
3	Dismantle the hopper, rotating disc, dosing cup and Collar from the machine and clean with clean dry lint free cloth. Put all the parts in a virgin polybag and transfer to washing area.		
4	Scrub all the above parts with nylon scrubber dipped in purified water and finally rinse all the parts with sufficient quantity of Purified water to remove any adhered material.		
5	Finally rinse all the cleaned parts with the 40-50 liters of purified water.		
6	Dry all the parts with compressed air followed by dry lint free cloth. Wipe all the parts with 70% v/v IPA Solution. Put all the cleaned parts in a virgin poly bag and transfer them to the designated area.		
7	Clean the vertical sealing roller and horizontal sealing plate with brass brush by applying silica compound followed by dry lint free cloth to remove all the adhered material.		
8	Clean the inner and outer surface of machine body, control panel, with wet lint free cloth followed by dry lint free cloth.		

Checked By (Production)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity performed and put 'X' if activity not performed.