



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Blister Pack Machine (Rotovac-210 V)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Blister Pack Machine (Rotovac- 210V).

### 2.0 SCOPE:

This procedure is applicable to the Cleaning and Operation of Blister Pack Machine in the Production Area.

### 3.0 RESPONSIBILITY:

Technical Associate : Operation  
Officer/ Executive Production : Supervision  
Head Production : SOP Compliance  
IPQA : Line Clearance

### 4.0 DEFINITION(S):

NA

### 5.0 PROCEDURE:

#### 5.1 "TYPE A" CLEANING:

**Change over from one batch to next batch of the same product and same potency.**

- 5.1.1 Ensure that all the materials of previous batch are removed from the blister-packing cubicle.
- 5.1.2 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.1.3 Record the cleaning start time in equipment usage log sheet as per SOP.
- 5.1.4 Clean the machine with dry lint free cloth and vacuum cleaner/dust extractor.
- 5.1.5 Clean the chute, hopper, vibration plate, and feeding roller and guide track with a dry lint free cloth.
- 5.1.6 Clean the conveyor belt and hatch with a dry lint free duster.
- 5.1.7 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine.
- 5.1.8 Record the cleaning end time in the equipment usage log sheet as per SOP. After completion of cleaning process, get it checked by production officer.

#### 5.2 "TYPE B" CLEANING:

**This is a cleaning procedure for Changeover of product with different actives/color/descending potency/ascending potency and if same product processed for more than a week or after maintenance.**



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- 5.2.1 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.2.2 Ensure that the power supply, chilled water supply and compressed air supply are put off.  
Clean the machine surface and product deposit area with dry lint free cloth and vacuum cleaner/dust collector.
- 5.2.3 Dismantle the hopper, hopper view glass, hopper lid, feed chute, feeding roller assembly, vibrating plate and guide track and transfer to washing area in virgin poly bag.
- 5.2.5 Flush the dismantled parts with purified water sufficient to remove powder. To remove the adhered particulate scrub the parts with nylon brush using purified water.  
NOTE: 2% Sodium Lauryl Sulphate (SLS) solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.
- 5.2.6 Finally rinse all the cleaned parts with the 20-30 liters of purified water.
- 5.2.7 Dry the cleaned parts with a dry lint free cloth.
- 5.2.8 Wipe the cleaned dismantled parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.
- 5.2.9 Remove the punching tool from the machine and clean with dry lint free cloth.
- 5.2.10 Place a crate below the forming unit and loosen upper bolt.
- 5.2.11 Remove the upper bolt and allow the water from the forming unit to drain and collect the water in a crate and discard it to washing.
- 5.2.12 Dismantle the forming drum and clean it with dry lint free duster.
- 5.2.13 Dismantle the gears of the batch code printing unit and main gears from the machine.
- 5.2.14 Clean them with dry lint free duster and cover with polybag and transfer to the packing spare cabinet.
- 5.2.15 Clean the sealing unit with a brass brush by applying silicon compound.
- 5.2.16 Clean the inner and outer surface of the machine, control panel and utility lines with a dry lint free cloth.
- 5.2.17 Wipe the machine with 70% v/v IPA solution followed by dry mopping with dry lint free cloth.
- 5.2.18 Clean the conveyor belt and hatch with a dry lint free duster.
- 5.2.19 Reassemble the cleaned hopper, chute and hopper lid.
- 5.2.20 Transfer the guide track, feeding chute to the packing spares cabinet.
- 5.2.21 Replace the "TO BE CLEANED" status label by "CLEANED" status label with date and sign of the production officer as per SOP.



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5.2.22 The cleaned equipment is idle for 72 hours, after this period wipe all the machine and parts with 70% v/v IPA solution before use. Previous "CLEANED" label shall be counter signed by production & QA officer with date as per SOP.

5.2.23 Record the cleaning operation time in equipment usage log sheet as per SOP and check the cleaning activity as per Annexure- I.

5.2.24 Clean the area as per SOP.

### 5.3 OPERATING PROCEDURE:

5.3.1 Ensure the area and equipment is clean. Affix 'UNDER PROCESS' label duly filled and signed on the machine and record all the observations in the equipment usage log sheet as per SOP.

#### 5.3.2 Equipment setting:

5.3.2.1 It consists of two set of reel support, reel fastening screw, reel adjusting screw, one PVC/PVDC foil sensor and one aluminium foil sensor all activities controlled by PLC.

#### 5.3.3 Loading of foil (PVC/PVDC and Aluminium foil):

5.3.3.1 Unscrew the reel fastening screws.

5.3.3.2 Adjust the back level control screw according to the width of forming foil.

5.3.3.3 Load forming material in such a manner that it should unwind in clockwise direction.

5.3.3.4 Tighten reel-fastening screw.

#### 5.3.4 Changing of PVC/PVDC foil:

5.3.4.1 Unscrew the reel fastening screws

5.3.4.2 Mount the foil by reel fastening screw and tight it.

5.3.4.3 End edges of wave are joints with edge of mounted roll and wrap them by cello tape.

#### 5.3.5 Procedure for fixing forming die:

5.3.5.1 Switch OFF the machine, PHR will lift up side.

5.3.5.2 Unscrew the centering bolt and fix the forming die on shaft guiding.

5.3.5.3 Tighten the forming die with screw in the star knob bolt till the almost reaches the face of the roller.

#### 5.3.6 Procedure for fixing Counter sealing Die:

5.3.6.1 Switch OFF the machine, PSR will lift up sides.

5.3.6.2 Counter sealing die is directly mounted on sealing station shaft

5.3.6.3 Clamped / tight with a close tolerance hub.

#### 5.3.7 Tablet feeding station:

5.3.7.1 It consists of hopper, vibrator, tablet level sensing proxy and sweep brush, feeding channel, universal feeder.

5.3.7.2 Speed of all vibrators is controlled independently by the controller provided in operator panel.



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### 5.3.8 Procedure for fixing of PHR:

- 5.3.8.1 Isolate the supply to the machine.
- 5.3.8.2 Loosen the bracket- clamping screw.
- 5.3.8.3 Fix the PHR assembly through tightens bracket-clamping screw.
- 5.3.8.4 Tilt the heater towards BFR and maintain gap 2-4mm (approx).
- 5.3.8.5 Switch on the machine.

### 5.3.9 Procedure for fixing PSR:

- 5.3.9.1 Isolate the supply to the machine.
- 5.3.9.2 Loosen the bolt of mounting bracket.
- 5.3.9.3 Hold pressure sealing roller assembly with right hand under the alignment bracket.
- 5.3.9.4 Lift the assembly above the CSR and gently introduce the mounting bracket in to the main shaft.
- 5.3.9.5 Fix the PSR assembly through tightens bracket-clamping screw.
- 5.3.9.6 Hold the PSR and gently allow lowering on to the CSR after the clamps maintain a gap of 5-7mm approx.

### 5.3.10 Embossing tool:

- 5.3.10.1 It consists of double electric crank, driven motor, servomotor, servomotor  
Driven indexing roller, sucking arms and web guide register roller and punch  
Safety sensor. It is situated below perforation station and process done by pneumatically controlled by PLC.

### 5.3.11 Operation

- 5.3.11.1 After line clearance from QA., put the ‘‘ UNDER PROCESS’’ label on the machine.
- 5.3.11.2 Enter start time of the machine in equipment usage log sheet as per SOP.
- 5.3.11.3 Switch ‘‘ON’’ the mains from electrical panel.
- 5.3.11.4 Blister packing of tablet shall be carried out in controlled area Temp =22<sup>0</sup>C ± 3<sup>0</sup>C and RH 50 ± 5 %).
- 5.3.11.5 Switch on the heater and adjust thermostat to provide the heating condition predetermined for the particular product as per mention in BPR.
- 5.3.11.6 Fix printed aluminium foil and PVC/PVDC foil rolls on the machine as per BPR.
- 5.3.11.7 Record the temperature of forming and sealing units in BPR.
- 5.3.11.8 Fill the inkpot into the overprinting kit of the machine with requisite height.
- 5.3.11.9 Affix the approved stereos/metal letters to the stereo drum of the BCP.
- 5.3.11.10 Unit/Embossing unit as per the instructions given in the BPR.
- 5.3.11.11 Check the sealing performance, overprinting/embossing and cutting of Strips and adjust if required.



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5.3.11.12 Affix the specimen of overprinted/embossed matter approved by production Officer and QA officer to BPR.

5.3.11.13 Cross check the containers of the product to be blistered are having 'APPROVED' Status label.

5.3.11.14 Cross check the weight of the product and record the total weight of the product on packing BPR.

5.3.11.15 Load the product to be blistered in the hopper, cover with lid and start the machine.

5.3.11.16 Machine to run the machine through PLC as follows.

### 5.3.12 Operation of PLC as per following instructions:

5.3.12.1 Switch "ON" the main switch.

5.3.12.2 MMI shows

Print

Alarm list

Login

Switch

Recipe

Log out Product data

PLCI/O

Help

5.3.12.3 Press log in and enter password.

5.3.12.4 Then press switch, MMI shows

- Run mode/JOG Mode

- Guard (Active/ Bypass)

- Vib. (Auto/Manu)

- PHR (ON/OFF)

- PSR (ON/OFF)

Heater Bypass

- Embossing (on/off)

- PRC-PRO

- PRC (ON/OFF)

- NFDS head

- NFD (Active/ Bypass)

- CE (Active/ Bypass)

- Spice Activate

- Clock Drift Enable

5.3.12.5 Press production data switch for editing of product detail like name /B.No. Mfd. and Exp. then screen display

- Good blister

- Rejected blister

- Machine run time

- Machine stop time

- Machine alarm stop

- Operator name

- B.No.

- Mfd.date

- Exp.date

- Reset production data



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5.3.12.6 Press Recipe for Edit, Save and Load, screen shows

- Current Recipe
- Load Recipe
- Edit and save Recipe
- Delete Recipe
- Display Recipe

5.3.12.7 Press display for setting of parameter like NFD count, No. of track, channels per track, CE error count, rejection enable count.

5.3.12.8 Pack release delay, PRC count etc.

5.3.12.8 Affix 'TO BE CLEANED' label on the machine and record all the observations in the equipment usage log sheet as per SOP.

### 5.3.13 Precaution:

5.3.13.1 Action at the time of machine stoppage during operation: At the time of machine stoppage the blister with product under the sealing roller should be cross marked with marker pen and removed manually at punching station and treated as rejected blisters and tablets.

**Procedure of marking of blisters:** For marking of blisters after stoppage, run the machine and marked the identified blister on the web (at lidding foil side) for proper identification and the same blister shall be collected from the conveyor belt after cutting of blisters at the cutting station.

5.3.13.2 When the machine is stopped during roll change, tea, lunch breaks, shift change over it must be ensured that no tablet is present in blister web up to cutting station

5.3.13.3 After the machine is restarted, a few empty blisters should run initially to ensure the overprinting details are clear. Empty blister should be removed for the line then packing started.

5.3.13.4 At the end of working shift the product left in hopper or vibratory bowl and channel should be removed, any blister lying on the packing line should also be removed.

**5.4** Setting and operating of camera: Set and operate the camera on Machine as per product refer SOP.

### 6.0 ABBREVIATION (S):

- IPA : Iso Propyl Alcohol  
SOP : Standard Operating Procedure  
v/v : Volume by Volume  
SLS : Sodium Lauryl Sulphate Solution



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### 7.0 REFERENCES (S):

SOP: Cleaning of production area.

SOP: Making entries in equipment usage and cleaning log sheet.

SOP: Status Labeling

SOP: Cleaning and Operation of Camera on Blister /Alu- Alu Machine

### 8.0 ANNEXURE (S):

Annexure – I: Cleaning checklist of blister pack machine (ROTOVAC 210V)

### 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 BLISTER PACK MACHINE (ROTOVAC 210V)

<b>Name of the Equipment</b>		<b>BLISTER PACK MACHINE (ROTOVAC 210V)</b>	
<b>Equipment I.D. No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	

S.No.	Activity	Activity Performed
1.	Clean the machine surface and product deposit area with dry lint free cloth and vacuum cleaner/dust extractor.	
2.	Dismantle the hopper, hopper view glass, hopper lid, feed chute, feeding roller assembly, vibrating plate and guide track and transfer to washing area in virgin poly bag.	
3.	Flush the dismantled parts with purified water sufficient to remove powder. To remove the adhered particulate scrub the parts with nylon brush using purified water. NOTE: 2% Sodium Lauryl Sulphate (SLS) solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.	
4.	Finally rinse all the cleaned parts with the 10-20 liters of purified water.	
5.	Dry the cleaned parts with a dry lint free duster.	
6.	Wipe the cleaned dismantled parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.	
7.	Remove the punching tool from the machine and clean with dry lint free cloth.	
8.	Place a crate below the forming unit and loosen upper bolt.	
9.	Remove the upper bolt and allow the water from the forming unit to drain and collect the drained water in the crate and discard it in washing area.	
10.	Dismantle the forming drum and clean it with dry lint free cloth.	
11.	Dismantle the gears of the batch code printing unit and main gears from the machine.	
12.	Clean them with dry lint free cloth and cover with polybag and transfer to the packing spare cabinet.	
13.	Wipe the machine surface and guide with 70% v/v IPA solution.	
14.	Clean the conveyor belt and hatch with a dry lint free duster.	

**Checked By (Prod.)**  
**Sign/Date**

**Verified By (QA)**  
**Sign/Date**

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