



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of De-Blistering machine	<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 the procedure for Cleaning and Operation of De-Blistering machine.

**2.0 SCOPE:**

This Procedure is applicable for Cleaning and Operation of De-Blistering machine in production area.

**3.0 RESPONSIBILITY:**

Technical Associate : Cleaning and Operation

Production : Officer / Executive / Assistant Manager

Head Production: To ensure execution & compliance

**4.0 PROCEDURE :**

**4.1 Procedure for cleaning :**

**4.1.1 TYPE A:**

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

4.1.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine as per SOP.

4.1.1.2 Ensure that the Deblistering Machine is switched OFF.

4.1.1.3 Dismantle the tablet collection tray from the de-blistering machine and remove the tablets and powder to the dedicated container.

4.1.1.4 Dry clean the Deblistering Machine body, tablet collection tray and utility cables using a dry lint free duster.

4.1.1.5 Fix the dismantled parts to the de-blistering Machine.

4.1.1.6 Replace 'UNDER CLEANING' status label with "CLEANED" status label with date and signature of the Production Officer.

4.1.1.7 Record the cleaning start time and end time activity in equipment usage log book as per SOP.



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**4.1.2 TYPE B:**

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

- 4.1.2.1 Follow the Procedure from step 4.1.1.1 to 4.1.1.2
- 4.1.2.2 Dismantle the tablet collection tray, tablet discharge chute and place in a polythene bag and take it to washing area on a trolley.
- 4.1.2.3 Clean the dismantled parts using with purified water.
- 4.1.2.4 Dry the dismantled parts using a lint free duster.
- 4.1.2.5 Fix the dismantled parts to the de-blistering Machine.
- 4.1.2.6 Replace 'UNDER CLEANING' status label with “CLEANED” with date and signature of the Production Officer.
- 4.1.2.7 Record the cleaning activity in equipment usage log book as per SOP.
- 4.1.2.8 Clean the area as per SOP.

**4.2 Frequency:**

- 4.2.1 Type 'A' cleaning is applicable after completion of every batch of same product.
- 4.2.2 Type 'B' cleaning is applicable in case of product change over.

**4.3 Equipment setting:**

- 4.3.1 Switch “ OFF “ the main from electric panel and remove the lower guard from pack entry side for access to support wheels.
- 4.3.2 Relieve the pressure between the support wheels and knurled roller by revolving the external adjusting segment
- 4.3.3 Loose screw of blister guides and adjust them to suit the pockets. Ensure that the center support wheel is exactly between the two rows of blister.
- 4.3.4 Loosen the side support wheels and adjust to coincide with the blister guides. For packs with minimal sealing margin, the side support rollers can be set 1mm within the blister guides to ensure proper grip.
- 4.3.5 Set the wheel spacing visually by inserting a pack in the blister guides rotate the motor by hand and observe the removal of tablet.

**4.4 Operation:**



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- 4.4.1 After the line clearance from QA, put the "UNDER PROCESS" label on the machine as per SOP.
- 4.4.2 Switch "ON" the mains from electric panel.
- 4.4.3 Blister packs are feed into the machine manually through blister guides and are taken up by the wheels and knurled roller.
- 4.4.4 The wheels are required to run between adjacent rows of product and offer support to the pack as the knurled roller expels the product from the pack.
- 4.4.5 The pressure between the wheels and roller, the packs are firmly held during the operation and expelled product will fall in to the receipt chute.
- 4.4.6 Enter the start time and completion time of batch in equipment usage log sheet as per SOP.
- 4.4.7 Switch "OFF" the main power supply from electric panel.
- 4.4.8 Affix 'TO BE CLEANED' label on the machine.

**Note:** If blister is not adjusted with the machine, then defoil the blisters manually.

### 4.5 **Precaution:**

- 4.5.1 Feed the packs into the machine with pack side parallel with the blister guides.
- 4.5.2 Apply sufficient pressure between the wheels and knurled roller to expel the product but avoid application of unnecessary pressure
- 4.5.3 Use wheels of adequate width, means sufficient clearance between rows of product to avoid damaging the product.

### 5.0 **ANNEXURE (S) :**

Nil

### 6.0 **REFERENCE (S) :**

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

SOP: Status labeling in production area

SOP: Procedure for are line Clearance.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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### 7.0 ABBREVIATION (S) /DEFINITION (S) :

IPA : Iso Propyl Alcohol

V/V : Volume / Volume

Q.A. : Quality Assurance

SOP : Standard Operating Procedure

### REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---