



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Sorter Elevator (SE-100)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down the procedure for the Cleaning and Operation of Sorter Elevator (SE-100).

### 2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of Sorter Elevator (SE-100) in production department.

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Operation
- 3.2 Officer/ Executive Production: Supervision
- 3.3 Head Production : SOP Compliance
- 3.4 IPQA : SOP Compliance and Line Clearance

### 4.0 DEFINITION (S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 "TYPE A" CLEANING

**This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.**

- 5.1.1 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.1.2 Enter the cleaning starting time in equipment usage log sheet as per SOP.
- 5.1.3 Ensure that the main power supply is switched 'OFF'.
- 5.1.4 Remove the adhered material on the SE-100 by using lint free cloth.
- 5.1.5 Clean the delivery pipe, hopper, acrylic plate, delivery chute, sorting plate etc. by using lint free cloth.
- 5.1.6 Record the cleaning activity in equipment usage log sheet as per SOP.
- 5.1.7 In case of common blend the change part used are of different sizes, then transfer and clean the sorting plate in general wash area with Type 'B' cleaning and proceed with next cleaned change



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part of product with Type 'A' cleaning as mentioned.

5.1.8 If the same product is processed for more than a week, then follow the procedure of cleaning as followed during product change over as per 'Type B' cleaning.

5.1.9 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production/QA Officer as per SOP.

### 5.2 "TYPE B" CLEANING:

**This is a cleaning procedure for Changeover of product with different actives / color / ascending potency / descending potency or after maintenance of contact parts.**

5.2.1 Follow the procedure from step 5.1.1 to 5.1.3.

5.2.2 Dismantle all the parts (delivery pipe, hopper, acrylic plate, delivery chute, sorting plate etc.) & put the all-dismantled parts in virgin polybag affix with "UNDER CLEANING" label & transfer them to respective cleaning area.

5.2.3 Clean the dismantled parts of the SE-100 using 3-5 liter of purified water with nylon brush.

5.2.4 Clean all the dismantled parts with 20-25 liters of purified water.

5.2.5 Apply a jet of purified water so as to ensure the complete removal of the previous product.

5.2.6 Wipe the machine surface of the SE-100 with wet duster soaked in purified water.

5.2.7 Dry the dismantled parts with a dry lint free duster.

5.2.8 Wipe all dismantled parts of the SE-100 and machine with 70% v/v IPA solution.

5.2.9 Affix label on SE-100 as "CLEANED" with date and signature of the Production Officer/QA officer.

5.2.10 Ensure that the area is cleaned as per SOP.

5.2.11 Record the cleaning activity end time of machine in equipment usage log 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.

5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / color / 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



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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 Assembling and setting

5.4.1.1 Assemble the delivery pipe and discharge chute, sorting plate on sheet and tight the acrylic cover with SS knob.

5.4.1.2 Fit the tray for capsule collection box below the MS bracket

**CAUTION:** Do not tighten the screws excessively as it can damage the acrylic plates.

#### 5.4.2 OPERATION:

5.4.2.1 Switch on the mains supply by operating the main switch in SE-100.

5.4.2.2 Switch the air blower motor and after 5 seconds switch on the vibrator motor.

5.4.2.3 The operation of delay time between two sections is due to avoid clogging of capsules in the venturi pipe.

5.4.2.4 The sorting plate sort out diametrically oversize, oval pinched and telescoped capsules.

5.4.2.5 The good capsules passed to the delivery pipe.

**NOTE:** Switch off the vibrator motor and after 10 seconds switch off the air blower motor.

#### 5.4.3 Dismantling

5.4.3.1 Loose the screw and remove the acrylic cover.

5.4.3.2 Remove the delivery pipe.

5.4.3.3 Remove the discharge chute.

5.4.3.4 Remove the sorting plate by unscrewing the knob.

5.4.3.5 Remove the rejected capsule collection box.



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### 6.0 ABBREVIATION(S):

- 6.1 SOP : Standard operating procedure
- 6.2 SS : Stainless Steel
- 6.3 MCS : Mini capsule Sorter
- 6.4 IPA : Iso Propyl alcohol
- 6.5 % : Percentage
- 6.6 v/v : Volume/Volume

### 7.0 REFERENCE (S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP: Cleaning Of Production Area.
- 7.3 SOP: Status Labeling

### 8.0 ANNEXURE(S):

- 8.1 NA

### 9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (S)** : Production Department (02), Quality Assurance (01)
- 9.3 **Reference copy (S)** : Production Department (01)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
1.	00	NA	New SOP	NA	NA