



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

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

### 1.0 OBJECTIVE:

1.1 To lay down the procedure for the Cleaning and operation of filled Capsule Elevator (FCE-100).

### 2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and operation of filled capsule elevator (FCE-100).

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation of machine  
3.2 Officer/ Executive Production : Supervision of cleaning and operation  
3.4 Head Production : SOP Compliance  
3.5 IPQA : SOP Compliance and Line clearance

### 4.0 DEFINITION (S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 "TYPE A" CLEANING

**Change over from one batch to next batch of the same product, same potency and of similar product with ascending 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 FCE-100 by using dry lint free cloth.
- 5.1.5 Clean the delivery chute, top pipe and bottom pipe by using lint free cloth.
- 5.1.6 Replace the "UNDER CLEANING" status label with "UNDER PROCESS" status label with date and signature of the Production Officer as per SOP.
- 5.1.7 Clean the area as per SOP.
- 5.1.8 Record the cleaning activity in equipment usage log sheet as per SOP.
- 5.1.9 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.



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### 5.2 "TYPE B" CLEANING

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

- 5.2.1 Follow the procedure from step 5.1.1 to 5.1.6
- 5.2.2 Transfer the above all parts in respective cleaning area.
- 5.2.3 Clean the dismantled parts of the FCE-100 using 5-7 liter of purified water with nylon brush.
- 5.2.4 Clean all the dismantled parts with 30-40 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 Dry the delivery chute by using compressed air.
- 5.2.7 Wipe the surface of the FCE-100 with wet duster soaked in purified water.
- 5.2.8 Dry the dismantled parts with a dry lint free duster.
- 5.2.9 Wipe all dismantled parts of the FCE-100 and machine surface with 70% V/V IPA solution.
- 5.2.10 Affix "CLEANED" label on machine with date and signature of the Production Officer/QA officer as per SOP.
- 5.2.11 Clean the area is cleaned as per SOP.
- 5.2.12 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 / 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, de-dusting 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 Assembling and setting:



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5.4.1.1 Fix bottom pipe to housing and tighten the screws.

5.4.1.2 Fix top pipe to bottom pipe with the help of split clamp.

5.4.1.3 Fix the delivery chute on the top pipe and tighten the screw. Adjust the angle of the chute in such a way so that all filled capsule fall in to the chute of metal detector.

### 5.4.2 OPERATION

5.4.2.1 Remove the CLEANED status label and affix 'UNDER PROCESS' label on the machine.

5.4.2.2 Switch "ON" the mains of the machine. Green indicator will glow.

5.4.2.3 Before given filled capsule in to the inlet chute, dry run the machine for few seconds. By switching 'ON' the filled capsule elevator.

### 5.4.3 DISMANTLING

5.4.3.1 Switch 'OFF' the main switch to stop power supply

5.4.3.2 Remove filled capsule delivery chute by loosening the screws, on the side of filled capsule delivery pipe.

5.4.3.3 Remove bottom pipe from housing by loosening screws.

5.4.3.4 Remove lid of the empty capsule hopper.

### 6.0 ABBREVIATION(S):

6.1 SOP : Standard operating procedure

6.2 FCE : Filled Capsule Elevator

6.3 IPA : Isopropyl Alcohol

6.4 QA : Quality Assurance

6.5 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



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### 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
01	00	NA	New SOP	NA	NA