



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and operation of Mini Capsule Sorter (MCS-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 Mini Capsule Sorter (MCS-100).

### 2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and operation of Mini Capsule Sorter (MCS-100).

### 3.0 RESPONSIBILITY:

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

### 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 MCS-100 by using vacuum cleaner or dust extractor.
- 5.1.5 Clean all the dismantled parts with 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 and different size of capsule Clean the sorting plate, spacer, sorting drum in General wash with Type "B " cleaning and proceed next batch with cleaned change part as mentioned Type A cleaning .
- 5.1.8 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production Officer as per SOP.
- 5.1.9 Clean the area is cleaned as per SOP.
- 5.1.10 If the same product is processed for more than a week, then follow the procedure of cleaning as



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followed during product change over as per 'Type B' cleaning.

### 5.2 "TYPE B" CLEANING

**This is a cleaning procedure for Changeover of product with different actives / colour / ascending potency / 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 MCS-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 sorting plate, sorting drum by using compressed air.
- 5.2.7 Wipe the machine surface of the MCS-100 with wet duster soaked in purified water.
- 5.2.8 Dry the machine surface with a dry lint free duster.
- 5.2.9 Wipe all dismantled parts of the MCS-100 and machine surface, panel with 70% v/v IPA solution.
- 5.2.10 Affix 'CLEANED' label on MCS-100 as with date and signature of the Production Officer.
- 5.2.11 Ensure that 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.
- 5.2.13 Ensure that the area is cleaned as per SOP.
- 5.2.14 Record the cleaning activity of MCS-100 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



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sheet as per SOP.

**5.4 OPERATING PROCEDURE**

**5.4.1 Assembling and setting**

**A.** Plate sorter      **B.** Drum sorter

**5.4.1.1 Plate sorter ( Loose cap sorting section )**

**5.4.1.1.1** It consists of three plates and spacers. The assembly is mounted on the Support bracket of Vibrator and is bolted from the bottom side.

**5.4.1.1.2** Put the sorting plate on frame and put the spacer on the sorting plate and on this put the guide plate followed by cover plate and these plate should be in align and tighten by four knobs.

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

**5.4.1.1.3 Drum sorter assembly (Diametrically defective capsule Sorter assembly**

**5.4.1.1.4** It consists of the drum sorter which consist of eight sorting plates mounted between two aluminum flanges.

**5.4.1.1.5** The Drum sorter is keyed on a shaft and enclosed in a stainless steel housing

**Note:** Insert the defective capsule collection box in the tray.

**5.5 Operation:**

**5.5.1 Operation of plate sorter**

**5.5.1.1** For starting the plate sorter keep the regulator knob at Zero position and switch on the ON/OFF switch of the plate sorter.

**5.5.1.2** Then slowly turning the knob clockwise set it at middle position.

**5.5.1.3** The plate sorter starts vibrating. Ensure that the plate sorter should not make rattling noise.

**5.5.2 Operation of drum sorter:**

**5.5.2.1** Push the green push button .The drum sorter starts rotation in Clockwise direction. The capsule rotated in the Drum sorter, the capsule of oversize diameter or oval shape get trapped in the sorting plate and good capsule pass through and delivered to the ECS-100.

**5.5.2.2** The defective capsules clogged in the sorting plate, are removed by a nylon brush which is fixed at the top of the drum sorter in the Stainless steel housing.

**5.5.2.3** The defective capsules get collected in a tray, which should be removed manually. At an interval.

**5.6 Dismantling**

**5.6.1 Plate sorter**



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5.6.1.1 Loose and remove the screw and remove the spacer and sorting plate.

**5.6.2 Drum sorter**

5.6.2.1 Loose the bolt and remove the sorting drum.

**5.7 Other removable parts**

- a. Defective capsule collection box.
- b. Acrylic cover.
- c. Tray.
- d. Top cover.

**6.0 ABBREVIATION (S):**

- 6.1 SOP : Standard operating procedure
- 6.2 V/V : Volume/ Volume
- 6.3 IPA : Iso Propyl Alcohol
- 6.4 % : Percentage
- 6.5 ECS : Empty Capsule Sorter

**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