



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Empty Capsule Sorter (ECS-100/ANCHORMARK)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down the procedure for the Cleaning and operation of Empty Capsule Sorter (ECS-100/ANCHORMARK).

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and operation of Empty Capsule Sorter (ECS-100/ANCHORMARK) 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: 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 start 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 ECS by using lint free cloth.

5.1.5 Clean the capsule guide pipe, hopper by using lint free cloth.

5.1.6 Ensure that no previous batch capsules (filled/empty) are present in rejection box, capsule hopper and guide pipe.

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

5.1.8 Clean the area as per SOP.

5.1.9 Record the cleaning activity end time of machine in equipment usage log sheet as per SOP.



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- 5.1.10 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.
- 5.2 **“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 5.1.5.
- 5.2.2 Dismantle the hopper, vertical pipe, air diverter and capsule guide pipe.
- 5.2.3 Transfer the all dismantled parts in respective cleaning area, in fresh polybag affix with “UNDER CLEANING” label as per SOP.
- 5.2.4 **Dismantling**
- 5.2.4.1 **Dismantling of ECS-100**
- 5.2.4.1.1 Loose the screw (SS knob) and remove the acrylic cover.
- 5.2.4.1.2 Remove the hopper and then deflector pipe.
- 5.2.4.1.3 Remove the empty capsule collection bin.
- 5.2.4.2 **Dismantling of ANCHORMARK**
- 5.2.4.2.1 Open the filled capsule sorter outlet chute to remove the top hopper by turning it in clockwise direction.
- 5.2.4.2.2 Remove the vertical pipe by unscrewing the flange bolt.
- 5.2.4.2.3 Remove the air diverter, capsule guide pipe.
- 5.2.4.3 Clean the dismantled parts of the machine (Hopper, Vertical pipe, Air diverter and Capsule guide pipe) using 3-5 liter of purified water with nylon brush.
- 5.2.4.4 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 that the no remnant present of the previous product.
- 5.2.6 Wipe the machine surface with wet duster soaked with purified water.
- 5.2.7 Dry the dismantled parts with a dry lint free duster.
- 5.2.8 Wipe all dismantled parts of the ECS with 70% v/v IPA solution.
- 5.2.9 Affix “CLEANED” label on machine with date and signature of the Production Officer/QA officer as per SOP.
- 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.
- 5.2.12 In case the cleaned equipment is idle for 72 hours, then prior to use wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous “CLEANED” status label by production & QA officer with date as per SOP. Affix “CLEANED” status label on machine with date and signature of the Production Officer/QA officer as per SOP.



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5.3 Frequency

- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product. If same product is processed for more than a week (three days for granulation area), and then follow the procedure of type – B cleaning.
- 5.3.2 Type 'B' cleaning is applicable in case of product change over or same product is run for a week whichever is earlier or any major maintenance (Contact Part)
- 5.3.3 Cleaning is applicable in case of at the end of working day, de-dusting of machine with vacuum cleaner or dry lint free cloth.

5.4 OPERATING PROCEDURE

5.4.1 Assembling and Setting ECS-100:

- 5.4.1.1 Assemble the deflector pipe on capsule sorting device and fit the hopper on deflector pipe and then tight the acrylic cover with SS knob.
- 5.4.1.2 Fit the rejected capsule collection box below the deflector pipe.

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

5.4.2 Assembling and Setting ANCHORMARK:

- 5.4.2.1 Assemble the capsule guide pipe on capsule sorting device and fit the hopper on capsule guide pipe.
- 5.4.2.2 Fit the vertical pipe by tighten the flange bolt.
- 5.4.2.3 Fit the hopper on it by turning the anticlockwise direction.
- 5.4.2.4 Fit the rejected capsule collection box below the deflector pipe.

5.4.3 Operation

- 5.4.3.1 Switch on the main supply and put ON the main selector switch on Operating Panel. Main Switch : Main ON / OFF switch
 - Selector Switch : To start the machine in auto / manual mode
 - Selector Switch : To start / stop the capsule polishing machine
 - Selector Switch : To start / stop the Empty Capsule Sorter machine
 - Selector Switch : To start / stop the blower for unfilled capsule separator
- 5.4.3.2 Switch "ON" the switch for ECS.
- 5.4.3.3 Turn the dimmer stat in clockwise to increase the voltage and anti-clockwise to decrease the voltage.
- 5.4.3.4 The digital voltmeter will indicate voltage fed to the variable speed motor.
- 5.4.3.5 The motor starts and air comes out from the hopper pipe, the top outlet and the bottom outlet.
- 5.4.3.6 Operate the dimmer stat to change the airflow by change the voltage.
- 5.4.3.7 Adjustment of voltage:
 - 5.4.3.7.1 Take 20 filled capsules and add 5 empty capsules.



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- 5.4.3.7.2 Switch on the machine and adjust the voltage as required. Load the 20 filled and 05 empty capsules slowly in the hopper.
- 5.4.3.7.3 It will be observed that some empty capsules have been collected in the filled capsule collection bin.
- 5.4.3.7.4 Increase the voltage by 5 volts and repeat the trial. At a particular setting, not a single empty capsule appeared in the collection bin, on satisfactory performance, record as voltage as “**Lower Limit Voltage**”.
- 5.4.3.7.5 Set the voltage range such that the empty capsules will go to rejection bin. Higher voltage is denoted as “**Higher Limit Voltage**”.
- 5.4.3.7.6 All observations are to be record in Annexure-I (ECS VALIDATION) and Annexure-II (CHALLENGE TEST OF ECS).

Precautions:

- 1) During execution of challenge test ensure that filled capsule container is not under the delivery chute.
- 2) During execution of challenge test ensure that all empty capsules used for test are recovered.

6.0 ABBREVIATION (S):

- 6.1 SOP : Standard operating procedure
- 6.2 SS : Stainless steel
- 6.3 IPA : Iso-Propyl Alcohol
- 6.4 Q.A. : Quality Assurance
- 6.5 V/V : Volume/ Volume
- 6.6 ECS : Empty Capsule Sorter

7.0 RERERENCE (S):

- 7.1 SOP No.: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP No.: Cleaning Of Production Area.
- 7.3 SOP No.: Status Labeling
- 7.4 SOP No.: Operation and Cleaning of Empty Capsule Sorter (ANCHOR)

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	ECS VALIDATION		Log Book
Annexure II	CHALLENGE TEST OF ECS		Log Book

9.0 DISTRIBUTION:

- 9.1 Master Copy : Quality Assurance



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9.2 Controlled copy (S): Production department (02), Quality Assurance (01)

9.3 Reference copy (S): Production department (02)

10.0 REVISION HISTORY:

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



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ANNEXURE I ECS VALIDATION

Procedure:

- 1) Take 20 filled capsules (collected after product setting) and 05 empty capsules (collected from empty capsule hopper).
- 2) Adjust voltage as required and pass 20 filled capsules along with 05 empty capsules.
- 3) Collect the empty capsules and filled capsules from respective bin and reconcile.
- 4) In Row A write the collected capsules quantity at filled collection bin and in Row B write the quantity of capsules in rejection bin.
Note: Put remarks 'ok' when filled capsules collection bin have 20 and in rejection bin 05 empty capsules, if not put 'not ok' in remarks.
- 5) Voltage should be so that empty capsules will be rejected and filled capsules should not be rejected.
- 6) Set the voltage range such that the empty capsules will go to rejection bin.

DATE:		PRODUCT NAME:				BATCH No.:		
S.No.	SET VOLTAGE	OBSERVATION				DONE BY	CHECKED BY	REMARKS
		NO OF CAPSULES INTRODUCED FOR TEST		CAPSULES RECOVERED AFTER TEST				
		FILLED CAPSULES	EMPTY CAPSULES	NO OF CAPSULES AT FILLED CAPSULE COLLECTION BIN (A)	NO OF CAPSULES AT REJECTION BIN (B)			

Lower Limit Voltage: - _____ Higher Limit Voltage: - _____

Done By (Production): - _____ Verified By (QA): - _____

- Note:** 1) Freeze the limit of ECS voltage for individual product after completion of three batches.
2) Destroy the entire used capsule during ECS challenge and validation test.



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ANNEXURE II CHALLENGE TEST OF ECS

Procedure:

- Take 20 filled capsules (collected after product setting) and 05 empty capsules (collected from empty capsule hopper).
- Set the voltage as limit obtained from ECS validation and pass 20 filled capsules along with 05 empty capsules.
- Collect the empty capsules and filled capsules from respective bin and reconcile.
- Write the collected capsules quantity at filled collection bin in A and quantity in rejection bin in B.
Note: Put remarks 'ok' when filled capsules collection bin have 20 and 05 empty capsules in rejection bin, if not put 'not ok' in remarks.
Frequency: Start of operation. Repeat the test 03 times for each operation.
- Voltage should be so that empty capsules will be rejected and filled capsules should not be rejected.
- In-process for ECS voltage is to be performed after 01 Hours by production.

DATE:		PRODUCT NAME:		BATCH NO.:				
*Lower Limit Voltage:			*Higher Limit Voltage:					
S.No.	SET VOLTAGE	OBSERVATION				DONE BY	CHECKED BY	REMARKS
		NO OF CAPSULES INTRODUCED FOR TEST		CAPSULES RECOVERED AFTER TEST				
		FILLED CAPSULES	EMPTY CAPSULES	NO OF CAPSULES AT FILLED CAPSULE COLLECTION BIN (A)	NO OF CAPSULES AT REJECTION BIN (B)			
Start of operation Date: _____		20	5					
Start of operation Date: _____		20	5					
Start of operation Date: _____		20	5					

In-process for Voltage of ECS

Date	Time	Observed Voltage	Checked By	Remarks

- *Note: 1) Limit obtained after 03 validation batches.
2) Destroy the entire used capsule during ECS challenge and validation test.