



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Empty Capsule Sorter Elevator (ANCHOR)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for the Cleaning and operation of Empty Capsule Sorter Elevator (ANCHOR).

2.0 SCOPE:

This procedure is applicable to the Cleaning and operation of Empty Capsule Sorter Elevator (ANCHOR) in production department.

3.0 RESPONSIBILITY:

Technical Associate : Operation

Officer/ Executive Production : Supervision

Head Production : SOP Compliance

IPQA : Line Clearance

4.0 DEFINITION (S):

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 "TO BE CLEANED" 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 ECSE 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 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.

5.1.7 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production/QA Officer as per SOP.

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

5.1.9 Ensure that the area is cleaned as per SOP.

5.2 "TYPE B" CLEANING

This is a cleaning procedure for Change over of product with different actives / colour / ascending



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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 "TO BE CLEANED" label & transfer them to respective cleaning area.
- 5.2.3 Clean the dismantled parts of the ECSE using 5-10 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 ECSE 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 ECSE with 70% v/v IPA solution.
- 5.2.9 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production/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 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP.

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, 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 which ever is earlier.

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.

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



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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.

6.0 ABBREVIATION(S):

SOP : Standard operating procedure

SS : Stainless Steel

ECSE : Empty Capsule Sorter Elevator

IPA : Iso Propyl alcohol

% : Percentage

v/v : Volume/Volume

7.0 REFERENCE (S):

SOP No.: Making entries in equipment usage and cleaning log sheet.

SOP No.: Cleaning Of Production Area.

SOP No.: Status Labeling

8.0 ANNEXURE(S):

NA

9.0 DISTRIBUTION:

Master Copy : Quality Assurance

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