



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of De-duster cum Metal Detector	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of De-duster cum Metal Detector.

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of De-duster cum Metal Detector in Production Department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation
- 3.2 Production Officer / Executive : Checking cleaning /Operation and Challenge Test
- 3.3 Head Production : SOP Compliance
- 3.4 IPQA Person : Line Clearance & Cleaning Checklist

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 Replace ‘UNDER PROCESS’ label with ‘TO BE CLEANED’ label filled and signed by production officer. Record the cleaning start time in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.1.2 Unplug the electric connections.

5.1.3 Dry clean the De-duster cum metal detector body, control panel and utility cables using a dry lint free duster.

5.1.4 Wipe the test sample blocks (Ferrous, Non-ferrous and S.S or non-magnetic steel) used for metal detector challenge test with dry lint free cloth.

5.1.5 Replace the “TO BE CLEANED” status label with “CLEANED” status label with date and signature of Production Officer and verified by QA Officer.

5.1.6 Enter the cleaning details time in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).



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5.2 **“TYPE B” CLEANING: This is a cleaning procedure for changeover of product with different actives/colors/ascending potency/descending potency of similar product 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 the metal detector parts like acrylic view cover, Teflon flapper, S.S discharge chute, acrylic inlet chute parts and rejection box.

5.2.3 Dismantle the De-duster parts like S.S discharge chute, dust collection box, S.S cover over perforated spiral plate. Dismantle the central shaft and S.S plate by rotating the central shaft in Anti clockwise direction. Dismantle the perforated spiral plate assembly, S.S feed aperture and dismantle the bottom perforated S.S plate.

5.2.4 Keep all dismantled parts in fresh double lined polythene bags affixed with ‘TO BE CLEANED’ label and transfer to wash area.

5.2.5 Use pressure jet to clean the dismantled parts with 25 liters of purified water and scrub the inner side and outer side of all parts with help of nylon scrubber followed by rinse with the 15 liters of purified water.

5.2.6 Clean the above parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate solution, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water).

5.2.7 Wipe all dismantled parts of the deduster cum metal detector with 70% v/v IPA solution.

5.2.8 Keep all the cleaned dismantled parts in fresh double lined polythene bag / covered with fresh polythene bag with affixed “CLEANED” status label by production/QA officer in respective cubicle after ensuring the cleanliness of respective cubical.

5.2.9 Clean the control panel and utility wires of deduster cum metal detector with clean dry lint free cloth. Clean the base and body parts of deduster cum metal detector with dry lint free cloth followed by lint free cloth dipped in 70% v/v IPA.

5.2.10 Wipe the test sample blocks (Ferrous, Non-ferrous and S.S/non-magnetic steel) used for metal detector challenge test with dry lint free cloth and finally clean the blocks with lint free cloth dipped in 70 % v/v IPA solution.

5.2.11 Replace the “TO BE CLEANED” status label of machine with “CLEANED” status label duly filled and signed by Production Officer and verified by QA Officer.

5.2.12 Enter the completion time of cleaning in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.3 **Frequency:**



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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 changeover of product with different actives / colors / ascending potency / descending potency of same product, after maintenance of contact parts and if same product is run for more than a week. "Type B" cleaning to be performed after completion of batch.

5.3.3 Cleaning (Dedusting of machine with vacuum cleaner and dry lint free cloth) is applicable in case of at the end of working day.

5.3.4 Type-B Cleaning is idle for 72 hours, if machine is not used within 72 hours clean the machine "before use" with lint free duster dipped in 70%v/v IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again by production and QA officer. Record the activity in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.4 **Machine setting:**

5.4.1 Ensure cleanliness of area and equipment. Affix 'UNDER PROCESS' label dully filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.4.2 Adjust the height of the de-duster such that its inlet chute positions slightly below the outlet chute of compression machine by unlocking the locking knob and then lifting up / down the machine body and finally locking the locking knob.

5.4.3 Adjust the height of the metal detector by unlocking the locking knob and then lifting up/ down the machine body and finally locking the locking knob.

5.4.4 Adjust the position of metal detector coil by loosening the knob and then set the final position of coil such that metal detector's inlet chute positions slightly below the outlet chute of tablet de-duster and finally tight the knob.

5.5 **Operation:**

5.5.1 Connect the de-duster connecting wire to VFD box slot of metal detector. Switch ON the main power supply. Turn 'ON' the metal detector by rotating 'ON/OFF' knob on metal detector. Metal detector will produce the beep sound and opening screen will display on screen of control panel. At the mean time rejection flapper will open and finally close. Screen will show:

SIG: Value

THR: Value

5.5.2 Press 'SETUP' key on control panel. Display will show:

ENTER PROD.NAME: (*)

Press 'ENTER' key display will show:



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ENTER PASSWORD # 2 “* * * *”

5.5.3 Again press ‘ENTER’ key and use ‘◀▲▼▶’ keys on control panel to enter the password. Press ‘ENTER’ key to enter the product name. Display will show:

ENTER PROD.NAME: (*)

Product name

Enter product name by using ‘◀▲▼▶’ keys and press ‘ENTER’ key to save product name. Press ‘▶’ key display will show:

ENTER BATCH NUMBER:

5.5.4 Press ‘ENTER’ key to enter the batch number. Use ‘◀▲▼▶’ keys to enter the batch number as per BMR. Press ‘ENTER’ key to save the batch number.

Press ‘▶’ key display will show:

ENTER DEFECT THR. (*)

Value mV

5.5.5 Press ‘ENTER’ key to enter this value. Set the threshold signal at least 7-10 times higher than the product signal by pressing ‘◀▲▼▶’ keys. Press ‘ENTER’ key to save the value.

Press ‘▶’ key display will show:

ENTER DEFECT THR. (*)

Value mV

Press ‘▶’ key display will show:

ENTER HOLD DELAY: (*)

Value mSec

5.5.6 Press ‘ENTER’ key to enter the hold delay time. Use ‘◀▲▼▶’ keys to enter the hold delay time as per product requirement. Press ‘ENTER’ key to save the value.

Press ‘▶’ key display will show:

ENTER PROD.LIMIT: (*)

Value mV

5.5.7 Press ‘ENTER’ key and use ‘◀▲▼▶’ keys to enter the value. Press ‘ENTER’ key to save the value. Press ‘▶’ key display will show:

ENTER PROD.PAHSE: (*) DEG.

5.5.8 Press ‘ENTER’ key to enter this value according to product requirement. Use ‘◀▲▼▶’ keys to enter the value. Press ‘ENTER’ key to save the value. Press ‘▶’ key display will show:

DEDUSTER:

DISABLED

5.5.9 Press ‘▼’ to enable the deduster. Now display will show:



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DEDUSTER:

ENABLED

And deduster will start.

5.5.10 Press '▶' key display will show:

DEDUSTER:

POWER=Value

FRQ= Value Hz

5.5.11 Press the 'ENTER' key and use '◀▲▼▶' keys to set power and frequency values as per product requirement.

5.5.12 On completion of operation, disable the de-duster and turn OFF the ON/OFF knob of the metal detector.

5.5.13 Affix 'TO BE CLEANED' labels duly filled and signed on the machine and record all the observations in the equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.6 Metal Detector Challenge Test

5.6.1 Follow the step no.5.5.1 to 5.5.8; ensure the metal pieces identification number as written on boxes of metal pieces.

5.6.2 Pass all three blocks ferrous, non-ferrous and S.S one by one from inlet chute of metal detector.

5.6.3 All the test blocks should be rejected by the metal detector. Record the activity in respective BMR.

5.6.4 Collect the test samples from the rejection box and start the operation.

5.6.5 **Frequency:** Before start / end of production and after every four hours interval or as per frequency specified in BMR. Challenge test performed along with production. After completion of batch or end of shift collect the tablets during generation of challenge test and pass again through metal detector.

6.0 ABBREVIATION(S):

6.1 IPA : Iso-Propyl Alcohol

6.2 Q.A. : Quality Assurance

6.3 SOP : Standard Operating Procedure

6.4 V/V : Volume/Volume

6.5 RHS : Right Hand Side

6.6 LHS : Left Hand Side

6.7 BMR : Batch Manufacturing Record

7.0 RERERENCE (S):

7.1 SOP: Making entries in equipment usage and cleaning log sheet.



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8.0 ANNEXURE (S):

8.1 Nil

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 (13)

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