



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Metal Detector	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Metal Detector.

### 2.0 SCOPE:

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

### 3.0 RESPONSIBILITY:

3.1 Technical Associate: Cleaning and Operation of Metal Detector

3.2 Officer/ Executive Production: Checking Cleaning / Operation and Challenge test.

3.3 Head Production: SOP Compliance

3.4 IPQA: Cleanliness Checking and 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 Replace 'EQUIPMENT STATUS' label with 'UNDER CLEANING' 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 metal detector body, control panel and utility cables using a dry lint free duster. Wipe the test sample blocks (Ferrous. Non-ferrous and SS or non-magnetic steel) used for metal detector challenge test with dry lint free cloth.

5.1.4 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of Production Officer and verified by QA Officer.

5.1.5 Enter the cleaning completion time in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

**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.**



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- 5.2.1 Follow the procedure from step 5.1.1 to 5.1.2.
- 5.2.2 Dismantle the metal detector parts i.e. acrylic view cover, Teflon flapper, S.S discharge chute, acrylic inlet chute parts and rejection box.
- 5.2.3 Keep all dismantled parts in fresh polythene bag or cover with fresh polythene bag affixed with 'UNDER CLEANING' label and transfer it to wash area.
- 5.2.4 Use pressure jet to clean the dismantled parts with 15 liter of purified water. Scrub the parts with nylon scrubber followed by rinse with the 5 liter of purified water.
- 5.2.5 Clean the above parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz.(For 1liter 2% Sodium lauryl sulphate, take 20 g Sodium lauryl sulphate and dissolve in 1liter of purified water)
- 5.2.6 Wipe all dismantled parts of the metal detector with 70% v/v IPA solution.
- 5.2.7 Clean the control panel and utility wires of metal detector with clean dry lint free cloth. Clean the base and body parts of metal detector with dry lint free cloth followed by lint free cloth dipped in 70% v/v IPA.
- 5.2.8 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.
- 5.2.9 Replace the "UNDER CLEANING" status label of machine with "CLEANED" status label duly filled and signed by Production Officer and verified by QA Officer.
- 5.2.10 Keep all the clean dismantled parts in fresh polythene bag or covered with polythene bag affixed with duly filled 'CLEANED' status label by production/QA officer and transfer in respective cubicle after ensuring the cleanliness of respective area.
- 5.2.11 Enter the cleaning completion time in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

### 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 changeover of product with different actives / colours / ascending potency / descending potency of same product or after maintenance of contact parts or if same product is run for more than a weak, cleaning Type - B done 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.



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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” and batch can be run.

### 5.4 Machine setting:

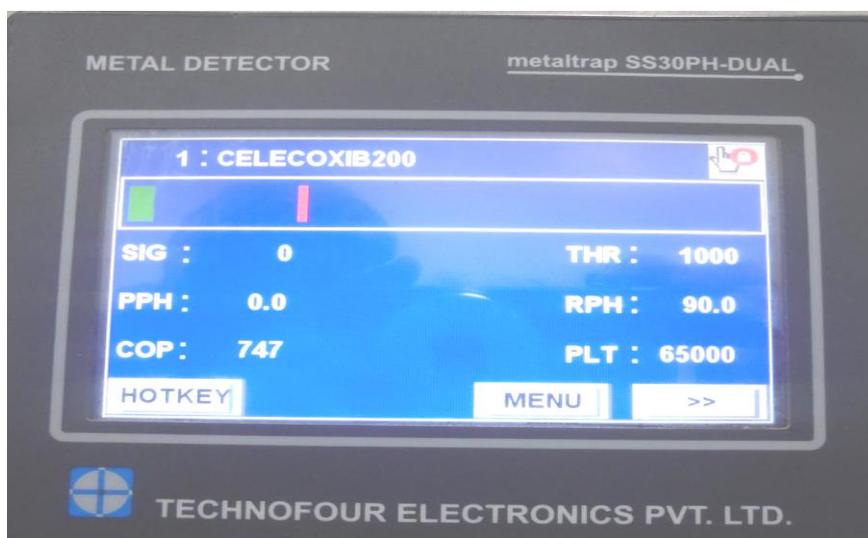
5.4.1 Ensure cleanliness of area and equipment. Affix ‘EQUIPMENT STATUS’ label dully filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP “MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET”.

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

5.4.3 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 filled capsule elevator and finally tight the knob

### 5.5 Operation

5.5.1 Turn “ON” the ON/OFF knob given on metal detector will turn “ON” and following screen will displayed:



5.5.2 Touch the sign given at top rightside corner of window (5.2.1) to open the lock for window and screen will be displayed as:

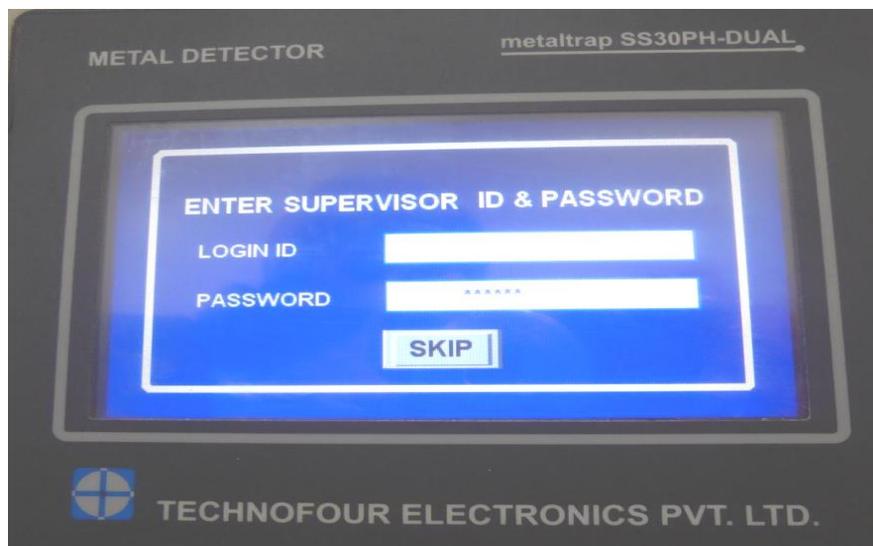


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5.5.3 Three different user ID and their password given with their right assignments as:

5.5.4 Enter the LOGIN ID and PASSWORD, screen will display:



5.5.5 Then set minimum possible THR value of machine which is 00050.

5.5.6 Set the RPH (reference for product phase angle) value by trial and error method that SMX value for product become minimum possible whereas with metal bids SMX value become maximum possible.

5.5.7 Pass separately five numbers of capsule/ tablet from metal detector one by one.

5.5.8 Record the SMX value for individual capsule/ tablet from 'LAST DEFECT INFORMATION' Screen which is given below:



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- 5.5.9 Consider the maximum obtained value from all the observed value.
- 5.5.10 Pass the ferrous block 0.3mm disc, record the SMX value.
- 5.5.11 Pass the Non-ferrous block 0.3mm disc, record the SMX value.
- 5.5.12 Pass the S.S block 0.5mm disc, record the SMX value.
- 5.5.13 Set the THR value in between the maximum SMX value obtained from the capsule/Tablet and minimum SMX value obtained with metal block by pressing the option THR from display.
- 5.5.14 Select the 'MENU' key from the following screen:



The following new screen will open:



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Select the 'PROD.LIBRARY' from the above screen to enter into the product library

5.5.15 New screen will open as following:



Select the 'SELECT PRODUCT' option if product recipe already saved

5.5.16 Following screen will open after pressing 'SELECT PRODUCT' option:



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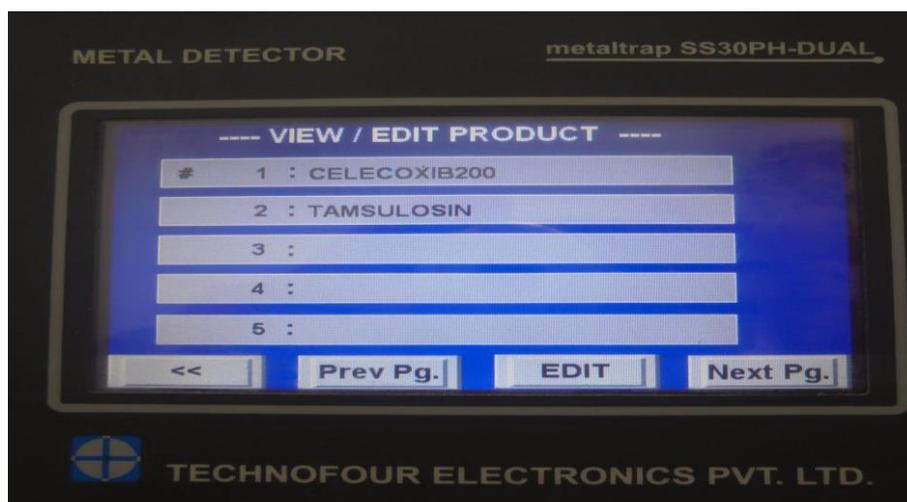


Select 'DELETE' option if previously saved recipe want to delete and select 'LOAD' option if already saved recipe required to load on machine.

5.5.17 To formulate new recipe select the 'VIEW/EDIT PRODUCT' option from following screen



New screen will open as following:





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Select the sr.no. and then 'EDIT' then provide all information required e.g. product name, B. No., THR value, RPH for respective product as in following screen.



### 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 (i.e. cubical name) 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 SS : Stainless Steel
- 6.4 V/V : Volume/Volume
- 6.5 SOP : Standard Operating Procedure
- 6.6 SMX : Signal Maximum
- 6.7 THR : Threshold

### 7.0 RERERENCE(S):

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



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7.2 SOP: Cleaning of Production Area.

7.3 SOP: Status Labeling

### 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 (02)

### 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