



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning Paste Preparation Kettle (Capacity 100 liters)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Paste Preparation Kettle (Capacity 100 liters).

### 2.0 SCOPE:

This SOP applies to the Cleaning and Operation of Paste Preparation Kettle in Production Department.

### 3.0 RESPONSIBILITY:

Technical associate : Cleaning and Operation

Officer and Executive: Supervision

Head Production : SOP compliance

IPQA Person : Line Clearance

### 4.0 DEFINITION (S):

NA

### 5.0 PROCEDURE

#### 5.1 Cleaning:

**This is a cleaning procedure for Change over of one batch to next batch/ product with ascending potency, product with different actives / colour / descending potency or after maintenance of contact parts.**

- 5.1.1 Remove "TO BE CLEANED" status label and Affix dully filled "UNDER CLEANING" status label on paste preparation vessel with date and signature of the Production Officer as per SOP.
- 5.1.2 Enter the cleaning start time of paste preparation vessel in equipment usage log sheet as per SOP.
- 5.1.3 Remove the detachable portion of the lid and the stirrer.
- 5.1.4 Load 50 – 60 Liters of purified water into the vessel and warm the water by opening the hot water inlet valve and soak for 15 minutes.
- 5.1.5 Scrub the inside, outside of vessel and lid of vessel with nylon scrubber to remove the adhered material.
- 5.1.6 Rotate the hand wheel towards anticlockwise to tilt the vessel and drain the water.
- 5.1.7 Clean the cleaned 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, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)



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- 5.1.8 Clean the inside, outside, steam cable, lid of paste preparation vessel and stirrer with 30 to 40 liters of purified water.
- 5.1.9 Dry the paste preparation vessel, lid and stirrer with the help of a dry lint free duster.
- 5.1.10 Wipe the paste preparation vessel and all the parts of vessel with 70% v/v IPA solution.
- 5.1.11 Rotate the hand wheel towards clockwise direction to bring the vessel to the original position.
- 5.1.12 Fix the stirrer and keep the lid over the paste preparation vessel.
- 5.1.13 Remove "UNDER CLEANING" label and Affix dully filled "CLEANED" label on vessel as with date and signature of the Production Officer & QA officer as per SOP.
- 5.1.14 Record the cleaning completion time of paste preparation vessel in equipment usage logbook as per SOP.
- 5.1.15 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.
- 5.1.16 Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP.
- 5.1.17 After unloading of the binder from Paste prepration vessel for every lot allow the equipment to cool and immediately Clean the equipment within 1 hour with purified water and scrub the vessel with nylon scrubber to remove the adhered binder to the vessel. Finally rinse with purified water to clean all the left over from the vessel, so that the vessel is ready for next lot. Record the cleaning activity time of paste preparation vessel in equipment usage logbook as per SOP.
- 5.2 Operation:**
- 5.2.1 Ensure the cleanliness of equipment and area.
- 5.2.2 After line clearance from QA, put "EQUIPMENT STATUS" label duly filled and signed on the machine as per SOP.
- 5.2.3 Enter the start time of the batch in equipment usage log sheet as per SOP.
- 5.2.4 Ensure that the main switch is in "ON" position.
- 5.2.5 Ensure that the limit switch is duly pressed.
- 5.2.6 Take the required quantity of Purified water into the vessel as specified in the Batch Manufacturing Record.
- 5.2.7 Open the hot water supply and return valve and start the heating of Purified water to the temperature specified in the Batch Manufacturing Record.



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- 5.2.8 Start the agitator by pressing the “Slow” button, the agitator will start rotating in clockwise direction in slow speed. Now slowly add the slurry into the vessel
- 5.2.9 Close the hot water valve after desired translucent paste is obtained & operate the agitator at fast speed by pressing the “fast” button. Check the temperature of binder using temperature probe.
- 5.2.10 Cool the binder in paste vessel to the temperature specified in Batch Manufacturing Record.
- 5.2.11 Unload the binder into prelabeled, cleaned S.S. container by tilting the paste vessel with the help of the hand wheel.
- 5.2.12 Remove “EQUIPMENT STATUS” label and Affix duly filled “TO BE CLEANED” label on the paste preparation Kettle as per SOP.
- 5.2.13 Enter the process completion time in equipment usage log sheet as per SOP.

### 5.3 Precaution and check points

- 5.3.1 Do not overheat the binder.
- 5.3.2 Ensure that the agitator is rotating in a clockwise direction.
- 5.3.3 Ensure that blade is not in contact of the vessels surface.
- 5.3.4 Ensure no any droplet of purified water is present in paste preparation vessel.

### 6.0 ABBREVIATION (S):

- S.S. : Stainless Steel.
- SOP : Standard Operating Procedure
- No. : Number
- IPA : Iso Propyl Alcohol
- v/v : Volume/Volume
- SLS : Sodium Lauryl Sulphate

### 7.0 RERERENCE (S):

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

### 8.0 ANNEXURE (S):

NA



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