



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Cleaning and Operation Paste Preparation Kettle (Capacity 150 liters) | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for cleaning and Operation of paste preparation kettle (Capacity 150 liters).

2.0 SCOPE:

This SOP applies to the cleaning and Operation of paste preparation kettle (Capacity 150 liters) 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/color/descending potency or after maintenance of contact parts.

5.1.1 Remove the "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 Fill up to 3/4th level of purified water into the vessel and warm the water by opening the steam 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 Tilt the vessel forward with the handle and lock at that position and drain the water.

5.1.7 Clean the inside, outside, steam cable, lid of paste preparation vessel and stirrer with 30 to 40 liters of purified water.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Cleaning and Operation Paste Preparation Kettle (Capacity 150 liters) | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

- 5.1.8 Dry the paste preparation vessel, lid and stirrer with the help of a dry lint free duster.
- 5.1.9 Wipe the paste preparation vessel and all the parts of vessel with 70% v/v IPA solution.
- 5.1.10 Unlock the vessel to bring the vessel to the original position with the help of handle.
- 5.1.11 Fix the stirrer and keep the lid over the paste preparation vessel.
- 5.1.12 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.
- 5.1.13 Record the cleaning completion time of paste preparation vessel in equipment usage logbook as per SOP.
- 5.1.14 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.
- 5.1.15 Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP.
- 5.1.16 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.
- 5.2.3 Enter the start time of the batch in equipment usage log sheet as per SOP.
- 5.2.4 Rotate the red selector switch to on position. Set the Required temperature through Temperature controller TC Set Points push buttons as specified in respective BMR.
- 5.2.5 Take the required quantity of Purified water into the vessel as specified in the Batch Manufacturing Record.
- 5.2.6 Rotate the heating selector switch in clockwise direction i.e. on position ‘1’ and steam start coming to the jacket of the vessel and start the heating of Purified water upto temperature specified in respective Batch Manufacturing Record.
- 5.2.7 Add the ingredients as per procedure specified in respective BMR.
- 5.2.8 Switch on the stirrer by pressing the green push button.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Cleaning and Operation Paste Preparation Kettle (Capacity 150 liters) | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

- 5.2.9 The stirrer will start rotating in clockwise direction.
- 5.2.10 Rotate the stirrer till the Binder of required consistency is obtained as specified in respective BMR.
- 5.2.11 Stop the steam by rotating the red selector switch to '0' position. Steam stop coming in the jacket.
- 5.2.12 Cool the binder in paste vessel to the temperature specified in Batch Manufacturing Record.
- 5.2.13 Stop the stirrer by pressing the red push button on control panel.
- 5.2.14 Unload the binder into labeled, cleaned S.S. container by tilting the paste vessel forward direction with help of handle provided and lock the vessel at that position.
- 5.2.15 Remove "EQUIPMENT STATUS" label and Affix "TO BE CLEANED" label duly filled on the paste preparation Kettle.
- 5.2.16 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 RERERENCE (S):

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

7.0 ABBREVIATION (S):

- Q.A. : Quality Assurance
- S.S. : Stainless Steel.
- SOP : Standard Operating Procedure
- No. : Number
- IPA : Iso Propyl Alcohol
- v/v : Volume/Volume

8.0 ANNEXURE (S):

NA



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation Paste Preparation Kettle (Capacity 150 liters)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

9.0 DISTRIBUTION:

Master Copy : Quality Assurance

Controlled Copy (S): Production Department, Quality Assurance

Reference Copy (S): Production Department