



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation Paste Preparation Kettle (Capacity 50, 100, 150 & 350 liters)	<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 Paste Preparation Kettle (Capacity 50, 100, 150 & 350 liters).

### 2.0 SCOPE:

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

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation  
3.2 Officer and Executive: Supervision  
3.3 Head Production : SOP compliance  
3.4 IPQA Person : Line Clearance

### 4.0 DEFINITION (S):

NA

### 5.0 PROCEDURE:

#### 5.1 Cleaning procedure for 50 & 100 Liters Paste Kettle (RP Product)

**This is a cleaning procedure for Changeover 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 kettle with date and signature of Production Officer as per SOP "Status Labeling".
- 5.1.2 Enter the cleaning start time of paste preparation kettle in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.1.3 Remove the detachable portion of the lid and the stirrer/ beater.
- 5.1.4 Load 20 – 30 Liters (for 50 liter) 50-60 Liters (for 100 liters) of purified water into the kettle and warms the water by opening the hot water inlet valve and soak for 15 minutes.
- 5.1.5 Scrub the inside, outside of kettle and lid of kettle with nylon scrubber to remove the adhered material.
- 5.1.6 Rotate the hand wheel towards anticlockwise to tilt the kettle and drain the water.



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- 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)
- 5.1.8 Clean the inside, outside, steam cable, lid of paste preparation kettle and stirrer with 15 to 20 liters (in 50 liters) and with 30 to 40 liters (in 100 Liters) of purified water.
- 5.1.9 Dry the paste preparation kettle, lid and stirrer with the help of a dry lint free duster.
- 5.1.10 Wipe the paste preparation kettle and all the parts of kettle with 70% v/v IPA solution.
- 5.1.11 Rotate the hand wheel towards clockwise direction to bring the kettle to the original position.
- 5.1.12 Fix the stirrer and keep the lid over the paste preparation kettle.
- 5.1.13 Remove the "UNDER CLEANING" label and Affix dully filled "CLEANED" label on kettle as with date and signature of the Production Officer & QA officer as per SOP "Status Labeling".
- 5.1.14 Record the cleaning completion time of paste preparation kettle in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".
- 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 "Status Labeling".
- 5.1.16 Record the 70% v/v IPA cleaning time of equipment in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.1.17 After unloading of the binder from Paste preparation kettle for every lot allow the equipment to cool and immediately Clean the equipment within 1 hour with purified water and scrub the kettle with nylon scrubber to remove the adhered binder to the kettle. Finally rinse with purified water to clean all the left over from the kettle, so that the kettle is ready for next lot. Record the cleaning activity time of paste preparation kettle in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.2 Operation for 50 & 100 Liters Paste Kettle (RP Product):

- 5.2.1 Ensure the cleanliness of equipment and area.  
Note: Ensure absence of any droplet of purified water in paste preparation kettle.
- 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 "Making entries in equipment usage and cleaning log sheet".



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- 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 kettle 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.
- 5.2.8 Start the agitator by pressing the “Slow” button, the agitator will start rotating in clockwise direction in slow speed.
- 5.2.9 Now slowly add the slurry into the kettle.
- 5.2.10 Close the hot water valves 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.
- 5.2.11 Cool the binder in paste kettle to the temperature specified in Batch Manufacturing Record.
- 5.2.12 Unload the binder into pre-labeled, cleaned S.S. container by tilting the paste kettle with the help of the hand wheel.
- 5.2.13 Remove the “EQUIPMENT STATUS” label and Affix duly filled “TO BE CLEANED” label on the paste preparation Kettle.
- 5.2.14 Enter the process completion time in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

### 5.3 Cleaning for 100 Liters Paste Kettle (Anchor Mark):

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

- 5.3.1 Remove the “TO BE CLEANED” status label and Affix duly filled “UNDER CLEANING” status label on paste preparation kettle with date and signature of the Production Officer as per SOP “Status Labeling”.
- 5.3.2 Enter the cleaning start time of paste preparation kettle in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.
- 5.3.3 Remove the detachable portion of lid & beater. Load 50 – 60 Liters of purified water into the kettle and warm the water by opening the hot water inlet valve and soak for 15 minutes.
- 5.3.4 Scrub the inside, outside of kettle and lid of kettle with nylon scrubber to remove the adhered material.



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- 5.3.5 Rotate the hand wheel towards anticlockwise to tilt the kettle and drain the water.
- 5.3.6 Clean the inside, outside, steam cable, lid of paste preparation kettle and stirrer with 15 to 20 liters of purified water.
- 5.3.7 Scrub the beater and lid with nylon scrubber to remove the adhered material.
- 5.3.8 Dry the paste preparation kettle, lid and beater with the help of a dry lint free duster.
- 5.3.9 Wipe the paste preparation kettle and all the parts of kettle with 70% v/v IPA solution.
- 5.3.10 Rotate the hand wheel towards clockwise direction to bring the kettle to the original position.
- 5.3.11 Fix the beater and keep the lid over the paste preparation kettle.
- 5.3.12 Ensure that the area is cleaned as per SOP "Cleaning of Production area".
- 5.3.13 Remove "UNDER CLEANING" label and Affix label on kettle as "CLEANED" with date and signature of the Production Officer and QA officer.
- 5.3.14 Record the cleaning completion time of paste preparation kettle in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.3.15 NOTE: After Type-B cleaning, if machine is not used within 72 hours, clean the machine "before use", with the lint free duster dipped in 70% IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.3.16 After unloading of the binder from Paste preparation kettle for every lot allow the equipment to cool and immediately Clean the equipment within 1 hour with purified water and scrub the kettle with nylon scrubber to remove the adhered binder to the kettle. Finally rinse with purified water to clean all the left over from the kettle, so that the kettle is ready for next lot. Record the cleaning activity time of paste preparation kettle in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.4 Operation for 100 Liters Paste Kettle (Anchor Mark):

- 5.4.1 Ensure the cleanliness of equipment and area.
- Note: Ensure absence of any droplet of purified water in paste preparation kettle.
- 5.4.2 After line clearance from QA, put 'EQUIPMENT STATUS' label duly filled and signed on the machine.
- 5.4.3 Enter the start time of the batch in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.4.4 Ensure that the main switch is in "ON" position.



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- 5.4.5 Take the required quantity of Purified water into the kettle as specified in the Batch Manufacturing Record.
- 5.4.6 Open the hot water supply and return valve and start the heating of Purified water to the temperature specified in the Batch Manufacturing Record.
- 5.4.7 Slowly add the slurry into the kettle and operate the beater by operating the switch.
- 5.4.8 The beater will start rotating in clockwise direction slow or fast as required.
- 5.4.9 Close the hot water valve after desired translucent paste is obtained. Check the temperature of binder using temperature probe.
- 5.4.10 Cool the binder in paste kettle to the temperature specified in Batch Manufacturing Record.
- 5.4.11 Unload the binder into prelabeled, cleaned S.S. container by tilting the paste kettle with the help of the hand wheel.
- 5.4.12 Remove "EQUIPMENT STATUS" label and Affix "TO BE CLEANED" label duly filled on the paste preparation Kettle.
- 5.4.13 Enter the process completion time in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.4.14 Unload the binder into prelabeled, cleaned S.S. container by tilting the paste kettle with the help of the hand wheel.
- 5.4.15 Remove the "EQUIPMENT STATUS" label and Affix duly filled "TO BE CLEANED" label on the paste preparation Kettle.
- 5.4.16 Enter the process completion time in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.5 Cleaning for 150 Liters Paste Kettle (BECTOCHEM)

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

- 5.5.1 Remove the "TO BE CLEANED" status label and Affix dully filled "UNDER CLEANING" status label on paste preparation kettle with date and signature of the Production Officer as per SOP "Status Labeling".
- 5.5.2 Enter the cleaning start time of paste preparation kettle in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".



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- 5.5.3 Remove the detachable portion of the lid and the stirrer.
- 5.5.4 Fill up to 3/4<sup>th</sup> level of purified water into the kettle and warm the water by opening the steam inlet valve and soak for 15 minutes.
- 5.5.5 Scrub the inside, outside of kettle and lid of kettle with nylon scrubber to remove the adhered material.
- 5.5.6 Tilt the kettle forward with the handle and lock at that position and drain the water.
- 5.5.7 Clean the inside, outside, steam cable, lid of paste preparation kettle and stirrer with 30 to 40 liters of purified water.
- 5.5.8 Dry the paste preparation kettle, lid and stirrer with the help of a dry lint free duster.
- 5.5.9 Wipe the paste preparation kettle and all the parts of kettle with 70% v/v IPA solution.
- 5.5.10 Unlock the kettle to bring the kettle to the original position with the help of handle.
- 5.5.11 Fix the stirrer and keep the lid over the paste preparation kettle.
- 5.5.12 Remove “UNDER CLEANING” label and Affix dully filled “CLEANED” label on kettle as with date and signature of the Production Officer & QA officer as per SOP “Status Labeling”.
- 5.5.13 Record the cleaning completion time of paste preparation kettle in equipment usage logbook as per SOP “Making entries in equipment usage and cleaning log sheet”.
- 5.5.14 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 “Status Labeling”.
- 5.5.15 Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP “Making entries in equipment usage and cleaning log sheet”.
- 5.5.16 After unloading of the binder from Paste preparation kettle for every lot allow the equipment to cool and immediately Clean the equipment within 1 hour with purified water and scrub the kettle with nylon scrubber to remove the adhered binder to the kettle. Finally rinse with purified water to clean all the left over from the kettle, so that the kettle is ready for next lot. Record the cleaning activity time of paste preparation kettle in equipment usage logbook as per SOP “Making entries in equipment usage and cleaning log sheet”.
- 5.6 Operation for 150 Liters Paste Kettle (BECTOCHEM):**
- 5.6.1 Ensure the cleanliness of equipment and area.
- Note: Ensure absence of any droplet of purified water in paste preparation kettle.



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- 5.6.2 After line clearance from QA, put 'EQUIPMENT STATUS' label duly filled and signed on the machine.
- 5.6.3 Enter the start time of the batch in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.6.4 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.
- 5.6.5 Take the required quantity of Purified water into the kettle as specified in the Batch Manufacturing Record.
- 5.6.6 Rotate the heating selector switch in clockwise direction i.e. on position '1' and steam start coming to the jacket of the kettle and start the heating of Purified water up to temperature specified in respective Batch Manufacturing Record.
- 5.6.7 Add the ingredients as per procedure specified in respective BMR.
- 5.6.8 Switch on the stirrer by pressing the green push button.
- 5.6.9 The stirrer will start rotating in clockwise direction.
- 5.6.10 Rotate the stirrer till the Binder of required consistency is obtained as specified in respective BMR.
- 5.6.11 Stop the steam by rotating the red selector switch to '0' position. Steam stop coming in the jacket.
- 5.6.12 Cool the binder in paste kettle to the temperature specified in Batch Manufacturing Record.
- 5.6.13 Stop the stirrer by pressing the red push button on control panel.
- 5.6.14 Unload the binder into labeled, cleaned S.S. container by tilting the paste kettle forward direction with help of handle provided and lock the kettle at that position.
- 5.6.15 Remove "EQUIPMENT STATUS" label and Affix "TO BE CLEANED" label duly filled on the paste preparation Kettle.
- 5.6.16 Enter the process completion time in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.7 **Cleaning for 350 Liters Paste Kettle (BECTOCHEM):**

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





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- 5.7.1 Remove the "TO BE CLEANED" status label and Affix dully filled "UNDER CLEANING" status label on paste preparation kettle with date and signature of the Production Officer as per SOP "Status Labeling".
- 5.7.2 Enter the cleaning start time of paste preparation kettle in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.7.3 Remove the detachable portion of the lid and the stirrer/ beater.
- 5.7.4 Fill up to 3/4<sup>th</sup> level of purified water into the kettle and warm the water by opening the steam inlet valve and soak for 15 minutes.
- 5.7.5 Scrub the inside, outside of kettle and lid of kettle with nylon scrubber to remove the adhered material.
- 5.7.6 Rotate the hand wheel towards anticlockwise to tilt the kettle and drain the water.
- 5.7.7 Clean the inside, outside, steam cable, lid of paste preparation kettle and stirrer with 60 to 70 liters of purified water.
- 5.7.8 Dry the paste preparation kettle, lid and stirrer with the help of a dry lint free duster.
- 5.7.9 Wipe the paste preparation kettle and all the parts of kettle with 70% v/v IPA solution.
- 5.7.10 Rotate the hand wheel towards clockwise direction to bring the kettle to the original position.
- 5.7.11 Fix the beater and keep the lid over the paste preparation kettle.
- 5.7.12 Remove the "UNDER CLEANING" label and Affix dully filled "CLEANED" label on kettle as with date and signature of the Production Officer & QA officer as per SOP "Status Labeling".
- 5.7.13 Record the cleaning completion time of paste preparation kettle in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.7.14 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 "Status Labeling".
- 5.7.15 Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP "Making entries in equipment usage and cleaning log sheet".





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5.7.16 After unloading of the binder from Paste preparation kettle for every lot allow the equipment to cool and immediately Clean the equipment within 1 hour with purified water and scrub the kettle with nylon scrubber to remove the adhered binder to the kettle. Finally rinse with purified water to clean all the left over from the kettle, so that the kettle is ready for next lot. Record the cleaning activity time of paste preparation kettle in equipment usage logbook as per SOP “Making entries in equipment usage and cleaning log sheet”.

### 5.8 Operation for 350 Liters Paste Kettle (BECTOCHEM):

5.8.1 Ensure the cleanliness of equipment and area.

Note: Ensure absence of any droplet of purified water in paste preparation kettle.

5.8.2 After line clearance from QA, put ‘EQUIPMENT STATUS’ label duly filled and signed on the machine.

5.8.3 Enter the start time of the batch in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

5.8.4 Ensure that the main switch is in “ON” position.

5.8.5 Ensure that the limit switch is duly pressed.

5.8.6 Take the required quantity of Purified water into the kettle as specified in the Batch Manufacturing Record.

5.8.7 Open the hot water supply and return valve and start the heating of Purified water to the temperature specified in the Batch Manufacturing Record.

5.8.8 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 kettle.

5.8.9 Now slowly add the slurry into the kettle.

5.8.10 Close the hot water valves 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.

5.8.11 Cool the binder in paste kettle to the temperature specified in Batch Manufacturing Record.

5.8.12 Unload the binder into prelabeled, cleaned S.S. container by tilting the paste kettle with the help of the hand wheel.

5.8.13 Remove the “EQUIPMENT STATUS” label and Affix duly filled “TO BE CLEANED” label on the paste preparation Kettle.



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5.8.14 Enter the process completion time in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.9 Precaution and check points

- 5.9.1 Ensure that blade is not in contact of the kettles surface.
- 5.9.2 Ensure that the agitator is rotating in a clockwise direction.
- 5.9.3 Do not overheat the binder.

### 6.0 REFERENCE (S):

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

### 7.0 ABBREVIATION (S):

- 7.1 Q.A. : Quality Assurance
- 7.2 S.S. : Stainless Steel.
- 7.3 SOP : Standard Operating Procedure
- 7.4 No. : Number
- 7.5 IPA : Iso Propyl Alcohol
- 7.6 v/v : Volume/Volume
- 7.7 SLS : Sodium Lauryl Sulphate

### 8.0 ANNEXURE (S):

- 8.1 NA

### 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
01	00	NA	New SOP	NA	NA