



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Coating Solution Preparation Vessel	<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 Coating Solution Preparation Vessel.

### 2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of Coating Solution Preparation Vessel in the Production Area.

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning & Operation of Vessel  
3.2 Officer/ Executive Production : Supervision of Cleaning & Operation of Vessel  
3.3 Head Production : SOP Compliance  
3.4 IPQA : 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 Remove "UNDER PROCESS" label to the machine.  
5.1.2 Ensure that the main power supply is switched off on control panel & also check "OFF" position of emergency switch.  
5.1.3 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP (Status labeling).  
5.1.4 Record the cleaning start time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).  
5.1.5 Clean the inner surface of vessel with the help of dry lint free cloth.  
5.1.6 Clean the outer surface of vessel with dry lint free cloth followed by 70% v/v IPA.  
5.1.7 Production officer shall check the cleanliness.  
5.1.8 Remove the "TO BE CLEANED" label and affix a label on equipments as "CLEANED" with date and signature of the Production Officer and QA officer.



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5.1.9 Record the cleaning end time in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet). After completion of cleaning process, get it checked by production officer.

### 5.2 “TYPE B” CLEANING:

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

5.2.1 Affix dully filled “TO BE CLEANED” status label on equipment with date and Signature of the Production Officer as per SOP (Status Labeling).

5.2.2 Ensure that the main power supply is switched off on control panel & also check “OFF” position of emergency.

5.2.3 Clean the inner surface, outer surface and agitator with nylon scrubber and with the help of purified water.

5.2.4 Again clean with purified water and ensure that the total removal of adhered material of previous product and batch.

5.2.5 Clean the inner surface of vessel with dry lint free cloth followed by 70% v/v IPA.

5.2.6 Clean the outer surface of vessel with dry lint free cloth followed by 70% v/v IPA.

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

5.2.8 Record 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 change over of product with different actives / colour / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type - B done after completion of batch.

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% v/v 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).

### 5.4 OPERATING PROCEDURE:

5.4.1 Ensure that the equipment is cleaned.

5.4.2 After line clearance from QA, put the “UNDER PROCESS” label on the machine.



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- 5.4.3 Enter start time of the machine in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.4.4 Set the agitator RPM nil from the PLC.
- 5.4.5 After loading of solvent/purified water and coating material (as mentioned in the BMR), set the agitator RPM as required.
- 5.4.6 After completion of activity, switch "OFF" the machine by pressing "RED" button from control panel.
- 5.4.7 Enter end time of the machine in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

### 5.5 Precautions:

- 5.5.1 At the time of coating continue the agitator for proper mixing of coating solution.
- 5.5.2 Lock the wheel base at the time of preparation of coating solvent.

### 6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 v/v : Volume by Volume
- 6.4 NLT : Not less than

### 7.0 REFERENCES(S):

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

### 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
1.	00	NA	New SOP	NA	NA