



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of 50 Ltrs. and 200 Ltrs. Manufacturing tanks	<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 the procedure for Cleaning and operation of 50 Ltrs. And 200 Ltrs. Manufacturing tanks.

### 2.0 SCOPE:

2.1 This procedure is applicable for cleaning and operation of 50 Ltrs. And 200 Ltrs. Manufacturing tanks.

### 3.0 RESPONSIBILITY:

- 3.1 Technical associate Production - For Execution
- 3.2 Officer/ Executive Production Department- For verification and implementation of SOP
- 3.3 Head Production Department- Ensure compliance of the SOP.

### 4.0 DEFINITION(S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 Cleaning

5.1.1 Checking Status labeling: Check the status "TO BE CLEANED" on equipment with details filled. If next product is the same as previous product (campaign production), follow batch-to-batch cleaning procedure. If next product is different from previous product, follow product-to-product cleaning procedure.

#### 5.1.2 Batch-to-Batch cleaning procedure ( Type A ) :

- 5.1.2.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label as per reference SOP (Status labeling).
- 5.1.2.2 Switch OFF the electric supply from tank's panel board.
- 5.1.2.3 Open outlet valves of tank and connect to drain point by flexible hosepipe.
- 5.1.2.4 Wash the inner surface of tank and stirrer with purified water by connecting purified water supply for five minutes or till there are no visible traces of the product.
- 5.1.2.5 Close the outlet valves after complete water is drained out.



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- 5.1.2.6 Mop the tank's outer surface with wet cloth followed by dry cloth.
- 5.1.2.7 After completion of cleaning activity, Put 'CLEANED' status label as per SOP (Status Labeling) having Equipment ID No./Area, Previous product, previous batch no., Done by Production and checked by QA with signature and date.
- 5.1.2.8 Record the details of cleaning in equipment usage sheet as per SOP (Making entries in equipment usage and cleaning log sheet)
- 5.1.3 **Product-to-product cleaning procedure (Type B):** This procedure is applicable if -there is a change in product, if the batches have been processed for 7 consecutive days, if the equipment is taken for maintenance during processing and maintenance work continues for more than 24 hrs or maintenance work involves any part, which comes in direct contact with product, If the equipment is not used within 72 Hrs, after type "A" Cleaning and If the equipment not used within 240 Hrs. (10 Days), after type "B" cleaning.
- 5.1.3.1 Switch OFF the electric supply from tank's panel board.
- 5.1.3.2 Open outlet valves of tank and connect to drain point by flexible hosepipe.
- 5.1.3.3 Wash the inner surface of tank and stirrer with purified water by connecting purified water supply for five minutes or till there are no visible traces of the product.
- 5.1.3.4 Take 50 liters. of purified water in 200 ltrs. Manufacturing tank / Take 30 liters. of purified water in 50 ltrs. Manufacturing tank and raise the temperature to 60-65°C. Circulate the hot water through wall of the tank for 5 minutes and drain the water completely.
- 5.1.3.5 Finally rinse the tank with 10 liter of purified water.
- 5.1.3.6 Inform the Q.A. to collect swab/rinse water sample if required and drain the water completely.
- 5.1.3.7 Close the outlet valves of tank.
- 5.1.3.8 Mop the tank's outer surface with wet lint free cloth followed by dry lint free cloth.
- 5.1.3.9 Record the details of cleaning in equipment usage log sheet and check the cleaning activity as per Annexure I (Cleaning checklist of 200 ltrs. Manufacturing tank) for 200 Ltr. Manufacturing tank and check the cleaning activity as per Annexure II (Cleaning checklist of 50 ltrs. Manufacturing tank) for 50Ltr. Manufacturing tank.
- 5.1.3.10 Protection of clean equipment: Shrink wrap or apply aluminium foil on all the ports, outlet points and tighten the manhole lid if the equipment is not planned for use within a day.
- 5.1.3.11 After completion of cleaning activity, Put 'CLEANED' status label as per SOP (Status Labeling) having Equipment ID No./Area, Previous product, previous batch no., Done by Production and checked by QA with signature and date.



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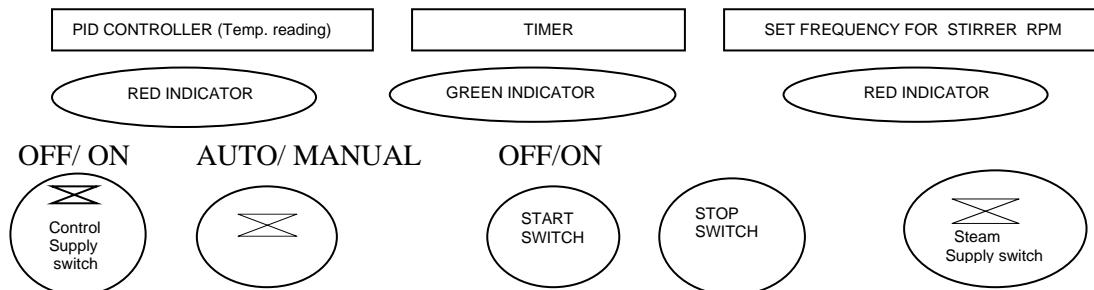
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### 5.2 Set Up:

#### 5.2.1 For 200 ltrs. Manufacturing tank:

- 5.2.1.1 Ensure that Manufacturing tank is cleaned.
- 5.2.1.2 Place the Manufacturing tank on designated place.
- 5.2.1.3 Attach the utility process line to Manufacturing tank as follow :
  - 5.2.1.3.1 Attach **1B** end of utility process line (SS line) with **2B** end of utility process line (SS line) With the help of clamp, Followed by **3B** end of utility process line (SS line) with one end of valve **No. 25** With the help of clamp.
  - 5.2.1.3.2 Connect the other end of **valve No. 25** With steam line / cooling line with the help of clamp.
  - 5.2.1.3.3 Attach **1T** end of utility process line ( SS line) with **2T** end of utility process line( SS line) With the help of clamp, Followed by **3T** end of utility process line ( SS line) with one end of **valve No. 26** With the help of clamp.
  - 5.2.1.3.4 Connect the other end of **valve No. 26** With steam line / cooling line with the help of clamp.
  - 5.2.1.3.5 Attach the temperature probe to Mfg. ltrs tank ( Bottom side of tank) and connect the temperature probe to panel board.
  - 5.2.1.3.6 Connect the compressed air to Panel board with compressed air pipe (Blue color) to regulate the steam supply.
  - 5.2.1.3.7 Connect the panel board to solenoid valve which is placed on steam supply with compressed air pipe (Blue color).
  - 5.2.1.3.8 Connect the panel Board to Mfg. tank for power supply.
  - 5.2.1.3.9 Panel Board For 200 Ltrs Manufacturing Tank:



#### 5.2.2 For 50 ltrs. Manufacturing tank:

- 5.2.2.1 For setup of 50 Ltr. Mfg tank follow the procedure from 5.2.1.1 to 5.2.1.3.8 except step 5.2.1.3.5.



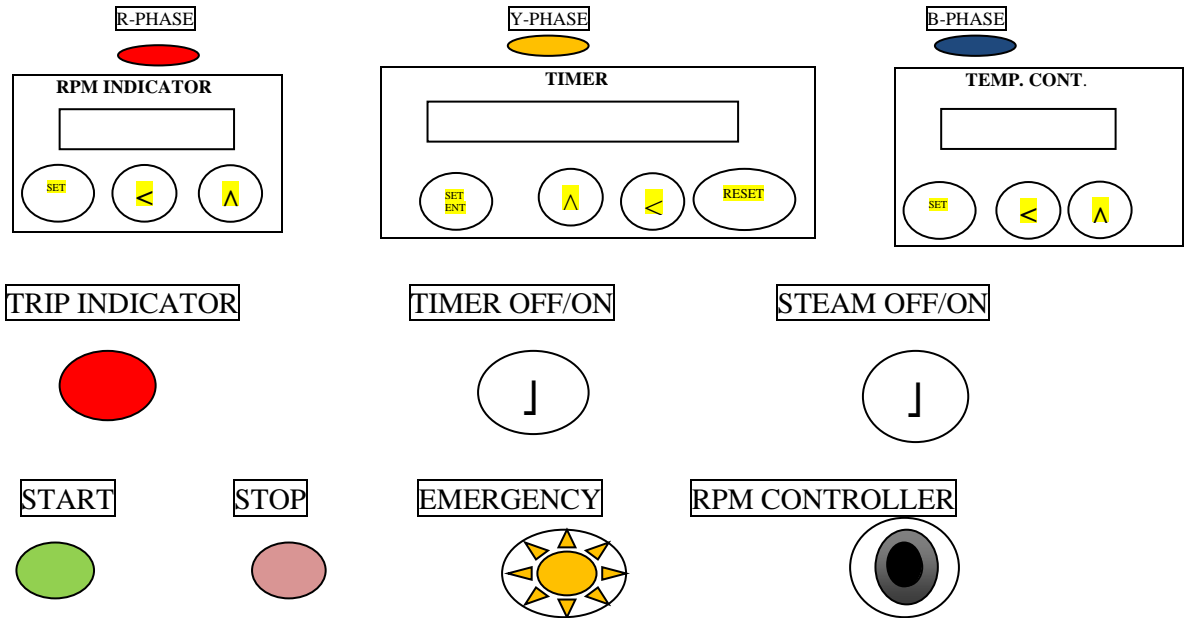
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### 5.2.2.2 PANEL BOARD FOR 50 Ltrs 's TANK:



5.2.3 Close the outlet valve of the mfg tank and fix blank on outlet line.

5.2.3.1 Open the bottom drain valve followed by air vent valve of tank's jacket and ensure that it is completely empty. Close air vent valve and drain valve of tank's jacket.

5.2.3.2 Switch 'ON' the electric supply from Mfg tank's panel board.

5.2.3.3 Set the temperature if required by pressing at a time the SET POINT key and increasing/decreasing (↓ / ↑) key.

5.2.3.4 Set the stirrer frequency / RPM (10 frequency ≈ 192 RPM) through VFD.

5.2.3.5 Switch 'ON' the compressed air valve from tank's panel to regulate the steam supply to tank jacket through solenoid valve.

5.2.3.6 Ensure that steam trap valve No 01 and 02 is open in initial stage until condensed water is removed and then after close the steam trap valve No 01.

5.2.3.7 After line clearance from QA put "EQUIPMENT STATUS" label as per SOP (Status Labeling) having Name of product, Batch no., Stage, Checked by Production with signature and date.

### 5.3 Operation



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### 5.3.1 In case manufacturing process require steam heating of materials

- 5.3.1.1 Load the material into the tank and switch ON the stirrer from the main panel.
- 5.3.1.2 Open the steam inlet valve.
- 5.3.1.3 Monitor the jacket pressure of the tank from pressure gauge fitted on the triclover valve throughout the operation, pressure should not be more than 2.0 Kg/cm<sup>2</sup> and temperature 90°C. If the pressure/Temperature exceeds the required limits, reduce the steam supply by adjusting steam inlet valve.  
As soon as the required temperature reaches start further process.
- 5.3.1.4 Continue the stirring until completion of the process.
- 5.3.1.5 After completion of process or required achieved temp.
- 5.3.1.6 Close the steam inlet valve.
- 5.3.1.7 Open the drain valve of tank's jacket from the bottom. Ensure the complete drainage
- 5.3.1.8 Of steam from the tank's jacket.

### 5.3.2 In case require cooling of materials

- 5.3.2.1 In case cooling of the content of tank is required after steam heating, first drain the Entire steam from the tank jacket by opening the drain valve of the tank jacket.
- 5.3.2.2 Open the outlet valve of cooling water from the top of the tank jacket followed by
- 5.3.2.3 Opening the inlet valve of cooling water from bottom.
- 5.3.2.4 Close the cooling water supply on attaining the required temperature.
- 5.3.2.5 After the completion of operation, Switch 'OFF' electric supply from panel board
- 5.4 Affix the status of "TO BE CLEANED" during NO activity and affix "UNDER CLEANING" during cleaning of the tank.
- 5.5 Record the details of operation of Mfg. tank in equipment usage record as per current version of SOP (Making entries in equipment usage and cleaning log sheet)
- 5.6 **NOTE:**
  - 5.6.1 Ensure water level in **COOLING POT** before start the stirrer.
  - 5.6.2 Ensure air pressure in the unit is not less than **4 Kg/cm<sup>2</sup>**.

### 6.0 ABBREVIATION (S):



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SOP : Standard Operation Procedure  
No. : Number  
BMR : Batch Manufacturing Record  
RPM : Revolution per minute  
VFD : variable frequency drive

### 7.0 REFERENCES:

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

### 8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning checklist of 200 ltrs. Manufacturing tank		Log Book
Annexure II	Cleaning checklist of 50 ltrs. Manufacturing tank		Log Book

### 9.0 DISTRIBUTION:

- 9.1 **Master copy** : Quality Assurance  
9.2 **Controlled copy ( s )** : Production department (01), Quality Assurance (01)  
9.3 **Reference copy ( s )** : Production department (01)

### 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



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### ANNEXURE I

#### CLEANING CHECKLIST OF 200 LTRS. MANUFACTURING TANK

**Name of the Equipment:** 200 ltrs. Manufacturing tank

**Previous product:**

**Batch No.:**

**Equipment I.D. No.:**

**Date:**

S.No.	Activity	Activity Performed
1.	Wash the inner surface of tank and stirrer with purified water by connecting purified water supply for five minutes or till there are no visible traces of the product.	
2.	Take 50 liters. of purified water in 200 ltrs. Manufacturing tank and raise the temperature to 60-65°C. Circulate the hot water through wall of the tank for 5 minutes and drain the water completely.	
3.	Close the outlet valves of tank.	
4.	Mop the tank's outer surface with wet cloth followed by dry lint free cloth.	

**Checked By (Production)**  
**Sign/Date**

**Verified By (QA)**  
**Sign/Date**

**Note:** Put '√' mark if activity performed and put "X" if activity not performed.



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### ANNEXURE II

#### CLEANING CHECKLIST OF 50 LTRS. MANUFACTURING TANK

**Name of the Equipment:** 50 ltrs. Manufacturing tank

**Date:**

**Equipment I.D.:**

**Previous product:**

**Batch No.:**

S.No.	Activity	Activity Performed
1.	Wash the inner surface of tank and stirrer with purified water by connecting purified water supply for five minutes or till there are no visible traces of the product.	
2.	Take 30 liters. of purified water in 50 ltrs. Manufacturing tank and raise the temperature to 60-65°C. Circulate the hot water through wall of the tank for 5 minutes and drain the water completely.	
3.	Close the outlet valves of tank.	
4.	Mop the tank's outer surface with wet lint free cloth followed by dry lint free cloth.	

**Checked By (Production)**  
Sign/date

**Verified By (QA)**  
Sign/Date

**Note:** Put '√' mark if activity performed and put "X" if activity not performed.