



Cleaning and Operation of Manufacturing Tank (Capacity-1000 ltrs.)

1.0 OBJECTIVE

To lay down the procedure for cleaning and operation of manufacturing tank (Capacity –1000 ltrs).

2.0 SCOPE

This procedure is applicable for cleaning and operation of manufacturing tank (Capacity –1000 ltrs).

3.0 RESPONSIBILITY

Technical associate Production - for Execution

Officer/ Executive Production Department- for verification and implementation of SOP

Head Production Department- shall ensure compliance of the SOP.

4.0 DEFINITION(S)

NA

5.0 PROCEDURE

5.1 Cleaning

5.1.1 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 change over procedure. If next product is different from previous product, follow product-to-product change over procedure.

5.1.2 Batch-to-Batch change over procedure (Type A):

5.1.2.1 Switch OFF the electric supply from tank’s panel board.

5.1.2.2 Open outlet valves of tank and connect to drain point by flexible hosepipe.

5.1.2.3 Wash the inner surface of tank with purified water by connecting purified water supply through High jet pressure jet cleaner to spray ball for five minutes or till there are no visible traces of the product.

5.1.2.4 Close the outlet valves after complete water is drained out.

5.1.2.5 Mop the tank’s outer surface with wet cloth followed by dry cloth

5.1.2.6 Put ‘CLEANED’ status label having Unit, Department, Equipment name, Cleaned by, Checked by Production Officer, Date and finally certified by Quality Assurance (QA) as per reference SOP.

5.1.2.7 Record the details of cleaning in equipment usage sheet as per reference SOP.

5.1.3 Product-to-product change over procedure (Type B): This procedure is applicable if -There is a change in product or during campaign production, 7 batches have been processed or 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.

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.



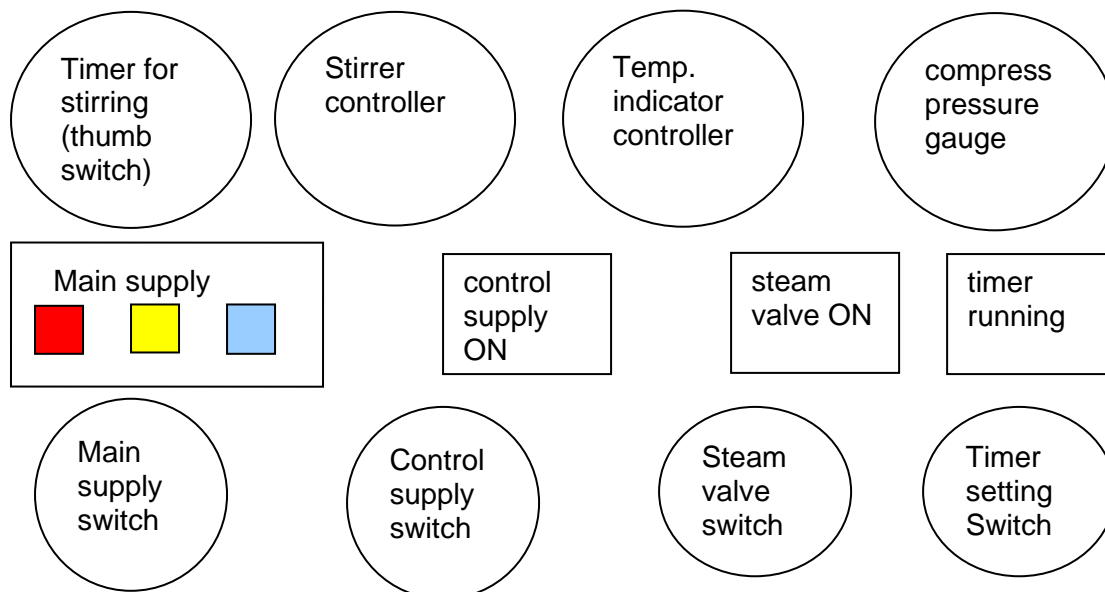
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- 5.1.3.3 Wash the inner surface of tank with purified water by connecting purified water supply through High jet pressure jet cleaner to spray ball for ten minutes or till there are no visible traces of the product.
 - 5.1.3.4 Open the triclover clamps and valves and clean them with purified water.
 - 5.1.3.5 Refit the valves and SS process lines and connect the tank to pump with flexible tubing.
 - 5.1.3.6 Take 300 liters. of purified water in 1000 ltrs. tank and raise the temperature to 60-65°C. Circulate the hot water supply through High jet pressure jet cleaner to spray ball for 10 minutes and drain the water completely.
 - 5.1.3.7 Finally rinse the tank with 30 liter of purified water.
 - 5.1.3.8 Inform the Q.A. to collect swab/rinse water sample if required and drain the water completely.
 - 5.1.3.9 Close the outlet valves of tank.
 - 5.1.3.10 Mop the tank's outer surface with wet cloth followed by dry lint free cloth.
 - 5.1.3.11 Record the details of cleaning in equipment usage sheet and check the cleaning activity as per Annexure I
 - 5.1.3.12 Protection of clean equipment: Shrink-wrap / aluminium foil all the ports, outlet points and tighten the manhole lid if the equipment is not planned for use within a day.
 - 5.1.3.13 Put 'CLEANED' status label having Unit, Department, Equipment name, Cleaned by, Checked by Production Officer, Date and finally certified by Quality Assurance (QA) as per reference SOP.
- 5.2 **Set up**
- 5.2.1 Ensure that manufacturing tank (capacity –1000 liters) is cleaned.
 - 5.2.2 After line clearance from Q. A. put "UNDER PROCESS" label on the equipment.
 - 5.2.3 Close the outlet valve of the tank and fix blank on outlet line
 - 5.2.4 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.
 - 5.2.5 Switch 'ON' the electric supply from tank's panel board.
 - 5.2.6 Set the temperature if required by pressing at a time the SET POINT key and increasing/decreasing (↓ / ↑) key.
 - 5.2.7 Fix the required RPM of stirrer by rotating knob in clockwise or anticlockwise direction on VFD.
 - 5.2.8 Switch 'ON' the compressed air valve from tank's panel to regulate the steam supply to tank jacket through solenoid valve.
 - 5.2.9 Ensure that steam trap valve No 01 and 02 is open in initial stage until condensed water is removed and then after close the valve No 01.



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5.2.10



5.3 Operation

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 Kgm/cm² and temperature 90°C. If the pressure/Temperature exceeds the required limits, reduce the steam supply by adjusting steam inlet valve.
- 5.3.1.4 As soon as the required temperature reaches start further process.
- 5.3.1.5 Continue the stirring until batch complete.
- 5.3.1.6 After completion of process or required achieved temp.
- 5.3.1.7 Close the steam inlet valve.
- 5.3.1.8 Open the drain valve of tank's jacket from the bottom. Ensure the complete drainage of steam from the tank's jacket.

5.3.2 Incase 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 opening the inlet valve of cooling water from bottom.
- 5.3.2.3 Close the cooling water supply on attaining the required temperature.
- 5.3.2.4 After the completion of operation, Switch 'OFF' electric supply from panel board

5.4 Affix the status of "TO BE CLEANED".

5.5 Record the details of operation of tank in equipment usage record as per current version of SOP.

5.6 **NOTE**



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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/cm²**.

6.0 ABBREVIATION (S)

SOP : Standard Operation Procedure

No. : Number

BMR : Batch Manufacturing Record

RPM : Revolution per minute

VFD : variable frequency drive

7.0 REFERENCES

SOP: Status labeling

SOP: Making entries in equipment usage and cleaning log sheet

8.0 ANNEXURE (S)

ANNEXURE I - Cleaning Checklist of Manufacturing tank (capacity-1000 ltrs)

9.0 DISTRIBUTION

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department, Quality Assurance

9.3 **Reference copy (s)** : Production department



PHARMA DEVILS

PRODUCTION DEPARTMENT

Cleaning and Operation of Manufacturing Tank (Capacity-1000 ltrs.)

ANNEXURE I

CLEANING CHECKLIST OF POT SIEVE

Name of the Equipment: Pot Sieve

Previous product:

Batch No. :

Equipment ID No.:

Date :

| S.No. | Activity | Activity Performed |
|-------|---|--------------------|
| 1. | Open outlet valves of tank and connect to drain point by flexible hose pipe. | |
| 2. | Wash the inner surface of tank with purified water by connecting purified water supply through High jet pressure jet cleaner to spray ball for ten minutes or till there are no visible traces of the product. | |
| 3. | Open the tri-clover clamps and valves and clean them with purified water. | |
| 4. | Refit the valves and SS process lines and connect the tank to pump with flexible tubing. | |
| 5. | Take 300 liters. of purified water in 1000 ltrs. tank and raise the temperature to 60-65°C. Circulate the hot water supply through High jet pressure jet cleaner to spray ball for 10 minutes and drain the water completely. | |
| 6. | Close the outlet valves of tank. | |
| 7. | Mop the tank's outer surface with wet cloth followed by dry lint free cloth. | |

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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