



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

To lay down the procedure for cleaning and operation of holding tank (capacity -3000 liters).

2.0 SCOPE:

This procedure is applicable for cleaning and operation of holding tank (Capacity –3000 liters) in Liquid department.

3.0 RESPONSIBILITY:

Technical associate Production - For Execution

Officer/ Executive Production - For verification and implementation of SOP

Head Production - Ensure compliance of the SOP.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Cleaning

5.1.1 After completion of batch affix “TO BE CLEANED” label and during cleaning affix “UNDER CLEANING” label, checked by production officer as per reference SOP (Status labeling). 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 and switch ON the electric panel of lube transfer pump.

5.1.2.2 Wash the inner surface of tank with purified water by connecting purified water to spray ball for five minutes and open outlet valves of tank and run the lube pump to circulate the water from transfer pipes to the tank.

5.1.2.3 Connect the drain pipe to the valve situated at the joint of transfer pipe of tank to the lube pump and put the other end of drain pipe to the drain opening.

5.1.2.4 Open the valve and drain the water completely, close the valve.

5.1.2.5 Clean the opening point of the holding tank with the help of purified water and nylon brush.



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STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.1.2.6 Again wash the inner surface of tank with purified water through spray ball for another 10 minutes or till there are no visible traces of product and continue the water circulation through lube pump from both the connected pipe line.
- 5.1.2.7 Open the valve and drain the water completely, Close the outlet valves after complete water is drained out and put dummy on the outlet valve by dismantle the S.S connection pipe, clean the connection pipe with the help of purified water and dry it with compressed air and kept it in inverted position on wall hanger of change part room. Cover the both opening of S.S connection pipe with aluminum foil.
- 5.1.2.8 Mop the tank's outer surface with wet cloth followed by dry cloth.
- 5.1.2.9 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 ("Status labeling").
- 5.1.2.10 Records: Record the details of cleaning in equipment usage sheet as per SOP ("Equipment usage and cleaning log sheet").
- 5.1.3 Product-to-product change over procedure (Type B):** his 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 Follow the process of type "A" Cleaning (from point No.5.1.2.1 to 5.1.2.6)
- 5.1.3.3 Open the valve and drain the water completely, close the valve.
- 5.1.3.4 Open the triclover clamps, valves and pipe. Transfer them in wash area and clean them with purified water and nylon brush.
- 5.1.3.5 Reconnect the valves and S.S process lines from the tank to lube pump.
- 5.1.3.6 Again wash the inner surface of tank with purified water by connecting purified water to spray ball for another five minutes and continue the water circulation from lube pump through connected SS pipe line. Open the valve to drain water completely and then close the valve.



PHARMA DEVILS

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STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.1.3.7 Take 500L of purified water in 3000L tank and raise the temperature to 60-65°C. Circulate the hot water by S.S transfer line from the lube pump through the spray ball (by connecting silicon pipe to the spray ball) and connecting SS pipeline (coming from filling and sealing machine area) for 10 minutes and drain the water completely. Close the outlet valves of tank. Dismantle the S.S connection pipe and put dummy on the outlet. Dismantle the silicon pipe from the spray ball and connect the S.S pipe to the holding tank. Dismantle the S.S connection pipe (between holding tank and lube pump), clean the connection pipe with the help of purified water and dry it with compressed air and kept it in inverted position on wall hanger in change part room and cover the both opening with aluminum foil.
- 5.1.3.8 Finally rinse the tank with 30 liter of purified water.
- 5.1.3.9 Inform the Q.A. to collect swab/rinse water sample if required and drain the water completely.
- 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 {"Cleaning checklist of holding tank (capacity-3000 liters), Format (current version)}.
- 5.1.3.12 Protection of clean equipment: Shrink wrap or apply aluminium foil on all the ports, outlet points and tightens 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 ("Status labeling").

5.2 Operation

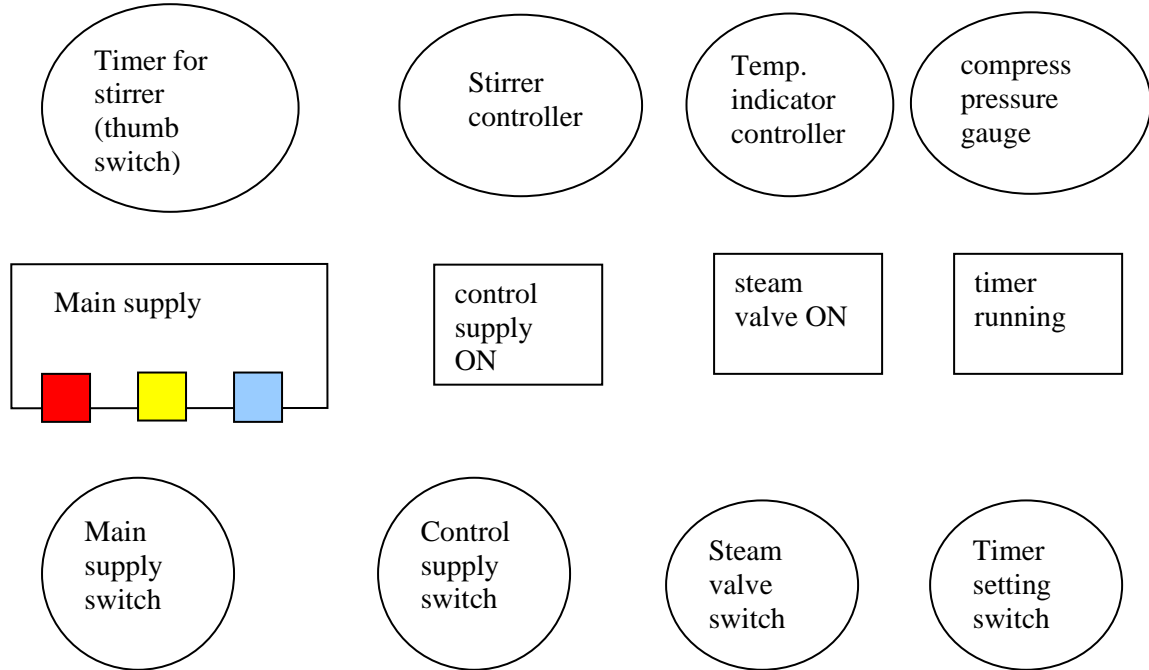
- 5.2.1 Ensure that Holding tank (capacity –3000 liters) is cleaned.
- 5.2.2 After line clearance from Q. A. put "EQUIPMENT STATUS" label on the equipment.
- 5.2.3 Close the outlet valve of the tank and fix blank on outlet line.
- 5.2.4 Start the transferring of bulk from manufacturing vessel through filter press.
- 5.2.5 After completion of transferring the bulk dismantle the S.S process line, clean it.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2.6



5.2.7 In case require steam heating :

- 5.2.7.1 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.
- 5.2.7.2 Switch 'ON' the electric supply from tank's panel board.
- 5.2.7.3 Set the temperature if required by pressing at a time the SET POINT key and increasing/decreasing (↓ / ↑) key.
- 5.2.7.4 Fix the required RPM of stirrer by rotating knob in clockwise or anticlock wise direction on VFD.
- 5.2.7.5 Switch 'ON' the compressed air valve from tank's panel to regulate the steam supply to tank jacket through solenoid valve.
- 5.2.7.6 Ensure that steam trap valve No 01 and 02 is open in initial stage until condensed water is removed and then after close the valve No 01.
- 5.2.7.7 Load the material / purified water into the tank and switch ON the stirrer from the main panel.
- 5.2.7.8 Open the steam inlet valve.
- 5.2.7.9 Switch 'ON' the electric supply from tank's panel board.
- 5.2.7.10 After the completion of operation, Switch 'OFF' electric supply from panel board.
- 5.2.7.11 Close the steam inlet valve.



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STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2.7.12 Open the drain valve of tank's jacket from the bottom. Ensure the complete drainage of steam from the tank's jacket

5.2.7.13 Affix the status of "TO BE CLEANED" during No activity and affix "UNDER CLEANING" during cleaning of the tank.

5.2.7.14 Record the details of operation of tank in equipment usage record as per current version of SOP ("Equipment usage and cleaning log sheet").

5.3 NOTE

5.3.1 Ensure water level in **COOLING POT before** start the stirrer.

5.3.2 Ensure air pressure in the unit is not less than **4 Kg/cm²**.

5.4 Operation

5.4.1 Ensure that Holding tank (capacity –3000 liters) is cleaned.

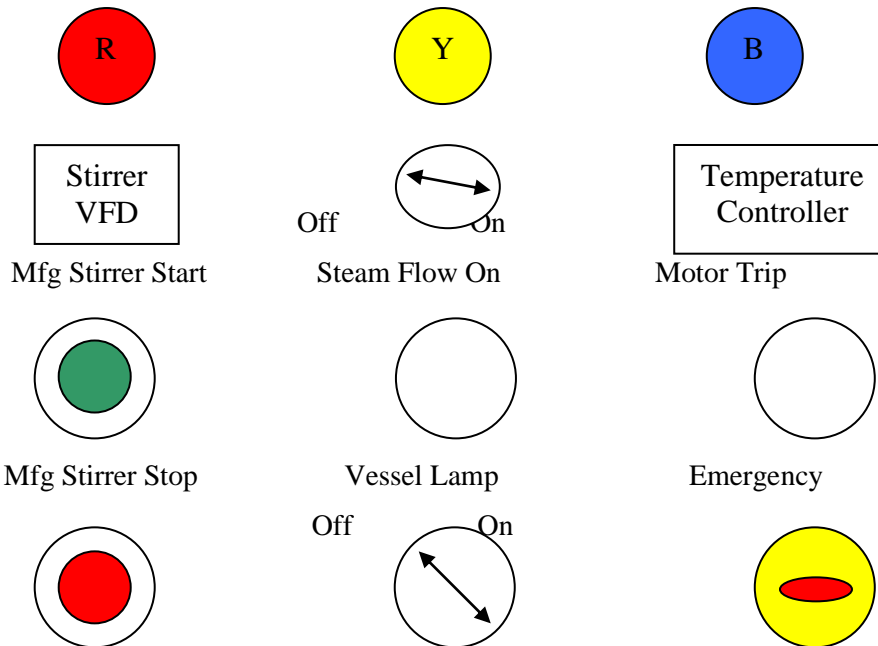
5.4.2 After line clearance from Q. A. put "EQUIPMENT STATUS" label on the equipment.

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

5.4.4 Start the transferring of bulk from manufacturing vessel through filter press.

5.4.5 After completion of transferring the bulk dismantles the S.S process line, cleaned it.

5.4.6



5.4.7 In case require steam heating :

5.4.7.1 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.



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PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.4.7.2 Switch 'ON' the electric supply from tank's panel board.
- 5.4.7.3 Set the temperature if required by pressing at a time the SET POINT key and increasing/decreasing (↓ / ↑) key.
- 5.4.7.4 Fix the required RPM of stirrer by rotating knob in clockwise or anticlock wise direction on VFD.
- 5.4.7.5 Open the compressed air valve for the steam supply to tank jacket through solenoid valve.
- 5.4.7.6 Ensure that steam trap valve No. 01 and 02 is open in initial stage until condensed water is removed and then after close the valve No 01.
- 5.4.7.7 Load the material / purified water into the tank and switch ON the stirrer from the main panel.
- 5.4.7.8 Open the steam inlet switch.
- 5.4.7.9 Switch 'ON' the electric supply from tank's panel board.
- 5.4.7.10 After the completion of operation, Switch 'OFF' electric supply from panel board.
- 5.4.7.11 Close the steam inlet switch.
- 5.4.7.12 Open the drain valve of tank's jacket from the bottom. Ensure the complete drainage of steam from the tank's jacket.
- 5.4.7.13 Affix the status of "TO BE CLEANED" during No activity and affix "UNDER CLEANING" during cleaning of the tank.
- 5.4.7.14 Record the details of operation of tank in equipment usage record as per current version of SOP (Making entries in equipment usage and cleaning log sheet).

5.4.8 NOTE

- 5.4.8.1 Ensure the water circulation in to the seal of stirrer before starting the stirrer.

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



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STANDARD OPERATING PROCEDURE

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Title: Cleaning and Operation of Holding tank (Capacity-3000 ltrs.)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

SOP: Equipment usage and cleaning log sheet.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no	Mode of Execution
ANNEXURE I	Cleaning checklist of holding tank (capacity-3000 liters)		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.	REVISION No.	CHANGE CONTROL No.	REASON (S) FOR REVISION	DETAILS OF REVISION	EFFECTIVE DATE



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Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

CLEANING CHECKLIST OF HOLDING TANK (CAPACITY-3000 LTRS)

Name of the Equipment: Holding tank (Capacity-3000 liters) **Equipment ID No.**

Previous product: **Batch No. :** **Date:**

S.No.	Activity	Activity Performed
1.	Wash the inner surface of tank with purified water by connecting purified water to spray ball for five minutes and open outlet valves of tank and run the lube pump to circulate the water from transfer pipes to the tank.	
2.	Connect the drain pipe to the valve situated at the joint of transfer pipe of tank to the lube pump and put the other end of drain pipe to the drain opening.	
3.	Open the valve and drain the water completely, close the valve.	
4.	Clean the opening point of the holding tank with the help of purified water and nylon brush.	
5.	Again wash the inner surface of tank with purified water through spray ball for another 10 minutes or till there are no visible traces of product and continue the circulation of water through lube pump from the both connected pipe line.	
6.	Open the triclover clamps, valves and pipe, SS connection pipe and transfer them in wash area and clean them with purified water and nylon brush.	
7.	Refit the valves and SS process lines and connect the tank to pump.	
8.	Again wash the inner surface of tank with purified water by connecting purified water to spray ball for another five minutes and continue the circulation of water through lube pump from both connected SS pipe line.	
9.	Take 500 liters of purified water in 3000 liters tank and raise the temperature to 60-65°C. Circulate the hot water by SS transfer line from the lube pump through to spray ball (by connecting silicon pipe to the spray ball) and connecting SS pipeline (coming from filling and sealing machine area) for 10 minutes and drain the water.	
10.	Close the outlet valves of tank.	
11.	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.