



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Procedure for Operation, Cleaning & Sanitization of Holding Tank/Vessel (Non-Jacketed)

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
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1.0 OBJECTIVE:

To lay down a procedure for Operation, Cleaning & Sanitization of Holding Tank/Vessel.

2.0 SCOPE:

This SOP is applicable for Operation, Cleaning & Sanitization of Holding Tank/Vessel.

3.0 RESPONSIBILITY:

Officer / Executive- Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

%	Percent
°C	Degree Celsius
BPCR	Batch Production and Control Record
Ltd.	Limited
NA	Not Applicable
PL	Production Liquid
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
RPM	Rotation per Minute
SOP	Standard Operating Procedure
SS	Stainless Steel
v/v	Volume by Volume

6.0 PROCEDURE:

6.1 OPERATION:

- 6.1.1 Ensure the Holding Tank is visually cleaned and line clearance performed by production as well as QA officer/executive.
- 6.1.2 Ensure the bottom discharge valve is properly closed and for its smooth working.
- 6.1.3 Connect one end of the detachable transfer pipe line to the outlet of the manufacturing tank via transfer pump and other end to the holding tank.
- 6.1.4 Transfer the bulk from the manufacturing tank to the holding tank through the bulk transfer line with the help of transfer pump,
- 6.1.5 Start the stirring process at desired RPM based on the product requirement (if applicable).



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6.1.6 At the time of filling, again transfer the hold bulk from the holding tank to the filling machine via transfer pipe line with the help of transfer pump in continuous stirring (if applicable based on product nature).

6.1.7 Record the bulk transferred detail in equipment log.

6.2 CLEANING:

6.2.1 BATCH TO BATCH CHANGE OVER (A TYPE CLEANING PROCEDURE)

6.2.1.1 Ensure the tank has a ‘TO BE CLEANED’ status label.

6.2.1.2 Previous product residue removes from the tank.

6.2.1.3 Take appropriate quantity of hot purified water (approx. 80-85°C temp.) in tank under stirring for 05 minutes.

6.2.1.4 After that open the drain valve to drain the hot purified water.

6.2.1.5 Again rinse the inner surface of the vessel with purified water and drain out.

6.2.1.6 Dry mop the outer surface of the tank with lint free cloth.

6.2.1.7 Affixed ‘CLEANED’ STATUS label to the tank.

6.2.1.8 Record the cleaning activity in equipment log.

A-Type cleaning is to be done for:

- Batch to batch changeover of the same product.
- Change over to higher strength of same colour.

6.2.2 PRODUCT TO PRODUCT CHANGE OVER (B- TYPE CLEANING PROCEDURE):

6.2.2.1 Ensure the tank has a ‘TO BE CLEANED’ status label.

6.2.2.2 Previous product residue removes from the tank

6.2.2.3 Take appropriate quantity of hot purified water (approx 80-85°C temp.) in tank under stirring for 05 minutes.

6.2.2.4 After that open the drain valve to drain the hot purified water.

6.2.2.5 Clean the inner surface of the vessel with solution of 2% v/v Extran MA 02.

6.2.2.6 Finally rinse the vessel with hot purified water and drain out.



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6.2.2.7 Ensure the cleanliness of the vessel visually.

6.2.2.8 Affixed “CLEANED” STATUS label to the tank.

6.2.2.9 Record the cleaning activity in equipment log

B-Type cleaning is to be done for:

- Product changeover
- Change over to lower strength of same product
- After 24 hours of A-Type cleaning before use.
- After maintenance or major breakdown.
- Change over to upper strength of different colour.
- If the equipment is not used within 72 hours then clean the vessel before use.
- After 3 batch of same campaign product.

6.3 HOT WATER SANITIZATION

6.3.1 Ensure the tank has a ‘TO BE CLEANED’ status label.

6.3.2 Take approx 200 liters of hot purified water at temp. 80-85°C in vessel and hold the water for 15 minutes inside the vessel under stirring.

6.3.3 Open the valve and drain the hot purified water.

6.3.4 Finally flush the vessel with purified water and drain out.

6.3.5 Dry mop the outer surface of the vessel with lint free cloth.

6.3.6 Collect the rinse water sample and send the sample to QC for chemical analysis.

6.3.7 If testing result does not comply with reference specification, again repeat the step for sanitization 6.3.2 to 6.3.5 and send the sample to QC till satisfactory result.

6.3.8 Affixed “CLEANED” STATUS label to the tank.

6.3.9 Record the sanitization activity in **Annexure-I**.

6.3.10 Sanitization shall be carried out after every B type cleaning.



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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Holding tank/Vessels Sanitization Record	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

