STANDARD OPERATING PROCEDURE

Title: Procedure for Cleaning and Sanitization of Transfer Pump (Lobe & Centrifugal) and Bulk Transfer Pipelines

SOP No.:		**Department:**	Production
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	1 of 4

1.0 OBJECTIVE:

To lay down a procedure for cleaning and sanitization of transfer pump (Lobe & centrifugal pump) and material transfer pipelines.

2.0 SCOPE:

This SOP is applicable for cleaning and sanitization of transfer pump (Lobe & centrifugal pump) and material transfer pipeline in manufacturing area.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

Ltd.	Limited
PL	Production Liquid
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 Procedure For Cleaning & Sanitization Of Transfer Pump And Material Transfer Pipelines:

6.1.1 Type-A Cleaning (Batch to Batch and Shift Closed):

6.1.1.1 Ensure the transfer pump (lobe pump & centrifugal pump) is 'OFF'

6.1.1.2 Affix the "TO BE CLEANED" label.

6.1.1.3 Dip the pipe in container filled with approx.50 liters of purified water and **'ON'** the pump. Allow the water to run through pipelines and pump.

6.1.1.4 After cleaning, collect the water in a glass beaker and check the clarity visually.

6.1.1.5 Clean the external surface of pump and pipelines and by moping with clean lint free cloth.

6.1.1.6 Mark the CLEANED status label

6.1.1.7 Maintain the record in Equipment log book.

Type-A Cleaning is to done for:

- Batch to batch changeover of same product/same colour.

- Change over to from lower strength to higher strength

6.1.2 Type-B Cleaning (Product to Product):

6.1.2.1 Ensure the tank has a 'TO BE CLEANED' status label.

6.1.2.2 Previous product residues remove from the tank.

6.1.2.3 Dip the pipe in container filled with approx.50 liters of purified water and **'ON'** the pump. Allow the water to run through pipelines and pump.

6.1.2.4 Then, flush freshly prepared Extran solution2% v/v through pipelines and pump by starting the pump.

6.1.2.5 Clean the external surface of pump and pipelines and by moping with clean lint free cloth

6.1.2.6 Finally, flush hot purified water through pipelines & pump to remove the trace of Extran solution.

Type-B Cleaning is to done for:

- Product changeover.
- Change over to lower strength of same product.
- After 48 hours of Type-A 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.

6.1.3 Sanitization:

6.1.3.1 Maintain the temperature of Purified water (80 - 85°C) in tank and then connect the transfer line to the tank.

6.1.3.2 Circulate the hot purified water from tank to the bulk transfer pipe line for approx. 15 minutes through the pump. After that flush the hot purified water.

6.1.3.3 Finally flush the fresh purified water to the tank and transfer pipeline and collect that water as Rinse /wash water sample for QC analysis.

6.1.3.4 Rinse/Wash water sample shall be sent to QC for analysis.

6.1.3.5 If the result does not comply, then repeat the cycle of cleaning from 6.1.2.3 to 6.1.2.6 and again collect the sample and send to QC for analysis.

6.1.3.6 If result complies then start the operation only after getting approval from QA Department.

6.1.3.7 If Maintain the sanitization record in **Annexure-I**.

Frequency: Sanitization shall be performed after every Type-B cleaning.

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sanitization Record of Transfer Pump (Lobe & Centrifugal) and Material Transfer Pipelines	

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:

GMP Guide lines

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

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ANNEXURE –I
SANITIZATION RECORD OF TRANSFER PUMP (LOBE & CENTRIFUGAL) AND MATERIAL TRANSFER PIPELINES

Area name: _____ **Transfer Pump ID: _____**

S.No.	Date	Time		Sanitization done by	Checked By: (Production)	Verified by (QA)	Remarks
		Start	End				

Frequency: Sanitization shall be performed after every Product change over or after 3 campaign batches of same product.