

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Production (External Preparation) SOP No.:				
Title: Cleaning and Sanitization of Transfer Pump, SS Tank, SS Pipe & Hose Pipe	<b>Effective Date:</b>			
Supersedes: Nil	<b>Review Date:</b>			
Issue Date:	Page No.:			

#### 1.0 OBJECTIVE:

To lay down a Procedure for Cleaning and Sanitization of Transfer pump, SS tank, SS pipe & Hose pipe.

#### 2.0 SCOPE:

This SOP is applicable for Cleaning and Sanitization of Transfer pump, SS tank, SS pipe & Hose pipe of Ointment Section.

#### 3.0 RESPONSIBILITY:

Production Officer/Executive

#### 4.0 ACCOUNTABILITY:

**Head-Production** 

#### 5.0 ABBREVIATIONS:

No. Number

S.S. Stainless Steel

SOP Standard Operating Procedure

#### **6.0 PROCEDURE:**

**6.1 PRECAUTION:** Use Hand Gloves and nose mask during the cleaning and Sanitization of Transfer pump, SS tank, SS pipe & Hose pipe.

#### 6.2 PROCEDURE FOR CLEANING & SANITIZATION OF TRANSFER PUMP:

- **6.2.1** Type A (Batch to Batch and shift Closed):
- **6.2.1.1** Remove the previous product label.
- **6.2.1.2** Unscrew the clamp and remove the product pipe line in bulk holding tank/multi mixture.
- **6.2.1.3** Clean the pipe and pump by purified water and dry mop externally by lint free Cloth.
- **6.2.1.4** Clean the pump body with lint free cloth.
- **6.2.1.5** Ensure that while cleaning there is no water contact with the electrical part of the pump.
- **6.2.1.6** Check & ensure the cleaning of transfer pump by production officer and affix the Cleaned status label.
- **6.2.1.7** Maintain the details of cleaning in the Equipment log book.
- **6.2.2** Type B (Product to Product):
- **6.2.2.1** Remove the previous product label.

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- **6.2.2.2** Unscrew the clamp and remove the product pipe line from bulk holding tank/multi mixer, unscrew the transfer pump part and clean the pipe line and pump by purified water.
- **6.2.2.3** Clean with hot purified water (75°C-80°C) while brushing if when / whenever required.
- **6.2.2.4** Now apply Extran MA02 solution 2% v/v and making sure that all parts are coming on contact with Extran MA02 solution.
- **6.2.2.5** Clean Extran MA02 solution with purified water using brushing / scrubbing the surface.
- **6.2.2.6** Rinse with hot purified water to remove Extran MA02 till there is no formation of foams is seen in drain water.
- **6.2.2.7** If foams are seen further rinse equipment with hot purified water.
- **6.2.2.8** Rinse the equipment further 3 times with purified water and dry with compressed air or dry lint free cloth.
- **6.2.2.9** Collect the sample and send to QC lab for rinse water analysis.
- **6.2.2.10** Affix "CLEANED" status label.
- **6.2.2.11** Maintain the details of cleaning in the Equipment log book.

#### 6.3 PROCEDURE FOR CLEANING & SANITIZATION OF SS TANK:

#### **6.3.1** Type A (Batch to Batch):

- **6.3.1.1** Remove the previous product label.
- **6.3.1.2** Remove the product in the SS tank and clean with purified water and dry mop externally by lint free cloth.
- **6.3.1.3** Clean the outer body of SS tank with lint free cloth.
- **6.3.1.4** Check & ensure the cleaning of SS tank by production officer and affix the cleaned status label.
- **6.3.1.5** Maintain the details of cleaning in the Equipment log book.

#### **6.3.2** Type B (Product to Product):

- **6.3.2.1** Remove the previous product label.
- **6.3.2.2** Remove the product in the SS tank and clean with purified water.
- **6.3.2.3** Unscrew the clamp and remove the product pipe line from bulk holding tank/multi mixer and clean the pipe line and pump by purified water.
- **6.3.2.4** Clean with hot purified water (75°C-80°C) while brushing if when / whenever required.



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- **6.3.2.5** Now apply Extran MA02 solution 2% v/v and making sure that all parts are coming on contact with Extran MA02 solution.
- **6.3.2.6** Wash Extran MA02 solution with purified water while brushing / scrubbing the surface.
- **6.3.2.7** Rinse with hot purified water to remove Extran MA02 till there is no formation of foams is seen in drain water when collected and shaken vigorously.
- **6.3.2.8** If foams are seen further rinse equipment with hot purified water.
- **6.3.2.9** Rinse the equipment further 3 times with purified water.
- **6.3.2.10** Collect the sample and send to QC lab for rinse water analysis.
- **6.3.2.11** Check & ensure the cleaning of SS tank by production officer and affix the cleaned status label.
- **6.3.2.12** Maintain the details of cleaning in the Equipment log book.

#### **6.3.3** B-Type Cleaning:

- **6.3.3.1** After 48 hrs of type A-Type cleaning.
- **6.3.3.2** Product Change Over.
- **6.3.3.3** Change over to Lower strength of same product.
- **6.3.3.4** After maintenance or major breakdown.
- **6.3.3.5** Change over to upper strength with different color.
- **6.3.3.6** If the Equipment is not used within 72 hrs clean the equipment before use.
- **6.3.3.7** After every 5 batches of same product in case of campaign product.
- **6.3.3.8** Maintain the details of cleaning in the Equipment log book.

#### 6.4 PROCEDURE FOR CLEANING & SANITIZATION OF SS PIPE AND HOSE PIPE:

#### 6.4.1 Procedure for cleaning.

- **6.4.1.1** SS pipe and hose pipe shall be brought to the washing area and remove the "To be cleaned label" from the SS pipe and hose pipe.
- **6.4.1.2** Wet the inner and outer surface of the SS pipe and hose pipe with Purified water and allow them such for minimum 3 minutes.
- **6.4.1.3** Scrub the inner and outer surface of the SS pipe and hose pipe with scrubber using purified water to remove any adhered material.
- **6.4.1.4** Now apply Extran MA02 solution 2% v/v and making sure that all parts are coming on contact with Extran MA02 solution.



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- **6.4.1.5** Wash Extran MA02 solution with purified water while brushing / scrubbing the surface.
- **6.4.1.6** Rinse with hot purified water to remove Extran MA02 till there is no formation of foams is seen in drain water when collected and shaken vigorously.
- **6.4.1.7** Dry the cleaned SS pipe and hose pipe with compressed air or dry lint free cloth.
- **6.4.1.8** Affix the Cleaned status label.
- **6.4.1.9** Transfer the SS pipe and SS hose pipe to the designated cleaning storage area.

#### 6.4.2 Procedure for Sanitization:

- **6.4.2.1** SS pipe and hose pipe shall be brought to the washing area and remove the "To be cleaned label" from the SS pipe and hose pipe.
- **6.4.2.2** Wet the inner and outer surface of the SS pipe and hose pipe with purified water and allow them such for minimum 3 minutes and outer surface of the SS pipe and hose pipe with scrubber using 80°c hot purified water to remove any adhered material.
- **6.4.2.3** Clean the outer and inner surface of the SS pipe and hose pipe with purified water.
- **6.4.2.4** Finally rinse the outer and inner surface of the SS pipe and hose pipe with purified water.
- **6.4.2.5** Dry the cleaned SS pipe and hose pipe with compressed air or dry lint free cloth.
- **6.4.2.6** Collect the sample and send to QC lab for rinse water analysis.
- **6.4.2.7** Affix the Cleaned status label.
- **6.4.2.8** Transfer the SS pipe and SS hose pipe to the designated cleaned storage area.
- **6.4.2.9** Maintain the details of cleaning in the Equipment log book Format.

#### 7.0 ANNEXURES:

ANNEXURE No.	ANNEXURE TITLE	FORMAT No.
Annexure-I	Cleaning and Sanitization of Transfer Pump, SS Tank,	
	SS Pipe & Hose Pipe	

**ENCLOSURES:** SOP Training Record

#### 8.0 DISTRIBUTION:

• Controlled Copy No. 01 Quality Assurance

• Controlled Copy No. 02 Production

Master Copy
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### 9.0 REFERENCE:

Not Applicable.

### 10.0 REVISION HISTORY:

### **CHANGE HISTORY LOG**

Revision No.	Change Control No.	<b>Details of Changes</b>	Reason for Change	Effective Date	Updated By



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# ${\bf ANNEXURE-I}$ CLEANING AND SANITIZATION OF TRANSFER PUMP, SS TANK, SS PIPE & HOSE PIPE

Area : Equipment ID No. : Month: Year :

Date	Time	Type of Cleaning A/B	Hot Water (80°C) Sanitization Done By	Checked By	Verified By