

## PHARMA DEVILS ENGINEERING DEPARTMENT

Title: Sanitization of Purified Water Generation System						
SOP No.:	Revision No.:	00				
Effective Date:	Supersedes No.	Nil				
<b>Review Date:</b>	Page No.	1 of 7				

## **1.0 OBJECTIVE:**

To lay down a procedure for Sanitization of Purified Water Generation System.

## **2.0 SCOPE:**

This SOP is applicable for Cleaning and Sanitization of Purified Water Generation system (CIP tank, Soft Water Storage tank, UF Membrane, UF Storage tank, RO Membrane, EDI).

## **3.0 RESPONSIBILITY:**

Operator / Officer / Executive – Engineering

## 4.0 ACCOUNTABILITY:

Head – Engineering

## 5.0 ABBREVIATIONS:

°C	Degree Centigrade
CIP	Clean in Place
EDI	Electron Di-ionization
NLT	Not less than
NaOcl	Sodium Hypochlorite
ID	Identification Number
Ltr	Liter
QA	Quality Assurance
QC	Quality Control
RO	Reverse Membrane
SOP	Standard Operating Procedure
UF	Ultra Filtration

### 6.0 **PROCEDURE**:

- 6.1 At first clean the CIP tank (before Sanitization of CIP tank) cleaning shall be performed as:
  - **6.1.1** Collect Purified water in CIP Tank for cleaning (for PW plant 3KL quantity of purified Water taken = 100Ltr. And for PW plant 5KL quantity of Purified Water taken = 150 ltr.)
    - 6.1.2 Flush the collected water by opening bottom drain valve & repeat this at least 2 times.
    - 6.1.3 Clean the tank externally for removal of dust & dirt if any.
    - 6.1.4 Record the CIP cleaning as per Annexure II. "CIP Tank Cleaning and Sanitization Record".

## 6.2 SANITIZATION PROCEDURE OF CIP TANK:

- **6.2.1** Fill the CIP tank of its Capacity with purified water.
- **6.2.2** Connect the house pipe of CIP pump to CIP tank for recirculation of hot Water.



## PHARMA DEVILS ENGINEERING DEPARTMENT

Title: Sanitization of Purified Water Generation System						
SOP No.:	Revis	sion No.:	00			
Effective Date:	Supe	rsedes No.	Nil			
Review Date:	Page	No.	2 of 7			

- **6.2.3** Switch on the heater to raise the temperature of Purified water inside the CIP Tank up to required temperature (NLT: 80°C).
- **6.2.4** After achieving temperature (NLT: 80°C), continue recirculate the hot water for 30 Minute.
- **6.2.5** After recirculation of hot water, drain the hot water from respective bottom drain valve of CIP tank and collect fresh purified water (full of its capacity) for flushing.
- **6.2.6** After completion of CIP cleaning and sanitization activity record the details as per annexure IV and after this CIP system shall be used for further sanitization activity in sequence as mention in below table.

S.No.	Sanitizing Part name	itizing Part name Temp. of Sanitization		Frequency	
1.	CIP System	NLT 80°C	30 min	Monthly	
2.	UF Membrane	NLT 80°C	60 min	Monthly	
3.	UF Storage Tank	NLT 80°C	60 min	Monthly	
4.	RO-I	NLT 80°C	60 min	Monthly	
5.	RO-II	NLT 80°C	60 min	Monthly	
6.	EDI	NLT 75°C	60 min	Monthly	

## 6.3 SANITIZATION PROCEDURE OF UF MEMBRANE:

- **6.3.1** Fill the CIP tank of its capacity with purified water.
- **6.3.2** Connect the CIP system to respective UF system with the help of hose pipes.
- **6.3.3** Switch on the heater of CIP tank to raise the temperature of collected water & start the circulation pump for recirculation of water.
- **6.3.4** After achieving temperature NLT 80°C, circulate this hot water for 60 minutes.
- **6.3.5** After completion of 60 minute sanitization cycle, drain the hot water through drain valve and remove the connected house pipe of CIP system and put the UF system in operation mode for flushing.
- **6.3.6** Flush the CIP tank with purified water after completion of sanitization activity.
- 6.3.7 Record the sanitization details of UF system as per Annexure –I "Sanitization Record".



# PHARMA DEVILS NGINEERING DEPARTMENT

Title: Sanitization of Purified Water Generation System					
SOP No.:	Revision No.:	00			
Effective Date:	Supersedes No.	Nil			
<b>Review Date:</b>	Page No.	3 of 7			

#### 6.4 SANITIZATION PROCEDURE FOR RO-I, RO-II & EDI SYSTEM:

- **6.4.1** Fill the tank of its capacity with purified water.
- 6.4.2 Hot water sanitization of 'RO I, II & EDI system' will be selected from control system. Sequence of complete sanitization cycle will be performed in 'Auto Mode' by SCADA control system.
- 6.4.3 Connect the CIP system to respective RO-I, RO-II and EDI system as mentioned in table (6.2.6) with the help of hose pipes.
- 6.4.4 Switch on the heater of CIP tank to raise the temperature of collected water & start the circulation pump for recirculation of water.
- 6.4.5 After achieving temperature (Refer table no. 6.2.6), circulate this hot water through recirculation pump of CIP system for given period of time (Refer table no. 6.2.6).
- 6.4.6 After completion of sanitization cycle, drain the hot water through drain valve and remove the connected house pipe of CIP system and put the system in operation mode for flushing and to blow down the temperature of RO membrane/EDI system.
- 6.4.7 Flush the CIP tank with purified water after completion of sanitization activity.
- 6.4.8 Record the sanitization details as per Annexure I "Sanitization Record".
- 6.4.9 Operator / Officer / Executive Engineering shall intimate QC to collect the sample for the analysis.
- 6.4.10 QC Team shall collect the sample from EDI Outlet sampling point (PW/SP-02 in 3 KL & PW/SP-04 in 5 kl purified water system plant) and submit the analysis report in Water system.

#### 6.5 **PROCEDURE FOR CLEANING OF SOFT WATER STORAGE TANK:**

- Prepare a 300/200 ltr. Solution of Sodium hypochlorite 200 ppm (0.02%) in CIP water 6.5.1 storage tank.
- **6.5.2** Calculate the quantity of chemical by below mention given formula:

# Water Quantity X Concentration of the Solution used = - - Kg or Ltr.

% assay of the solution



# PHARMA DEVILS

ENGINEERING DEPARTMENT

Title: Sanitization of Purified Water Generation System						
SOP No.:	Revision No.:	00				
Effective Date:	Supersedes No.	Nil				
<b>Review Date:</b>	Page No.	4 of 7				

- **6.5.3** Connect the CIP pump with soft water storage tank and recirculate the sodium hypochlorite solution for 1 hour from top to bottom continuously for one hour.
- **6.5.4** Drain out the water by opening the valve.
- **6.5.5** After carry out cleaning activity, rinse the soft water storage tank and connected lines. After rinsing activity flush the tank with soft water until its sample passes in free chlorine (Limit: NMT 0.5 PPM).
- **6.5.6** Free chlorine shall be tested/checked as per procedure defined in SOP.
- 6.5.7 Record the cleaning details in Annexure-III "Soft Water Storage Tank Cleaning Record".
- **6.5.8** Frequency: Monthly  $\pm$  7 Days or sanitization & cleaning activity shall be performed as per purified water system sanitization schedule.

## 7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT NO.
Annexure-I	Sanitization Record	
Annexure-II	CIP Tank Cleaning and Sanitization Record	
Annexure-III	Soft Water Storage Tank Cleaning Record	

**ENCLOSURES:** SOP Training Record

## 8.0 **DISTRIBUTION:**

- Controlled Copy No. 01
- Controlled Copy No. 02
- Master Copy

Quality Assurance Engineering Quality Assurance

## 9.0 **REFERENCES:**

Manual

## **10.0 REVISION HISTORY:**

## CHANGE HISTORY LOG

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

	9				PHA	RMA DEN VEERING DEPARTM	<b>/ILS</b> ENT				
Title: Saniti	zation of Purifi	ed Water Gene	ration System								
SOP No.:									Revision N	lo.:	00
Effective Da	ate:								Supersede	s No.	Nil
<b>Review Dat</b>	e:								Page No.		5 of 7
Area: Purified Wa	ter System ID	:			ANNE SANITIZAT	XURE – I FION RECC	ORD		]	Block: CIP pump ID	:
Date	Equipment Name	Sanitization Start Time	Water Collected For Sanitization	After achi circulat Start Time	ieving temp. tion Time End Time	Temp Start Time	erature Rea After 30 min.	ading End Time	Done By – Sign & Date	Review By Sign & Date	Remarks

Note: Temperature Limit for UF System, UF Storage Tank & RO System is NLT 80°C. Temperature Limit for EDI system is NLT 75°C.



# PHARMA DEVILS ENGINEERING DEPARTMENT

Title: Sanitization of Purified Water Generation System						
SOP No.:	Revision No.:	00				
Effective Date:	Supersedes No.	Nil				
<b>Review Date:</b>	Page No.	6 of 7				

## ANNEXURE – II CIP TANK CLEANING AND SANITIZATION RECORD

Area: Equipment Name:

## BLOCK: CIP Pump ID:

Date	Cleaning Time		Water collected	Sanitization Achieving Ter	n Time After np.(NLT-80°C)	Done By	Review
	Start Time	Endfor SanitizationStartEndTimeTimeTime			Date	& Date	

	PHARMA DEVILS ENGINEERING DEPARTMENT									
Title: Sa	Title: Sanitization of Purified Water Generation System									
SOP No	).:							Revision No.	.: 00	
Effectiv	ve Date:							Supersedes N	No. Nil	
Review	Date:							Page No.	<b>7</b> of	f 7
	ANNEXURE – III SOFT WATER STORAGE TANK CLEANING RECORD									
Purified	Water System ID:						Area:			
F reque	$\frac{1 \text{ Cy: Monthly } \pm 7 \text{ Days}}{1 \text{ Oty of Sodium}}$	<u>s</u>	<b>Circulation</b> T	ime of Sodium	Rinsing	Activity	Result of free			
Data	Hypo chlorite Sol.	Purified Hypochlorite Solution	ite Solution	Ti	Time chlorine after rinsing		Done By Sign & Reviewed B	Reviewed By	y Domonk	
Date	to make 200 ppm concentration	Taken	From	То	From	То	(Limit: 02 to 05 ppm)	Date	Sign & Date	Kelliark
		1	1	1 1		1	1	1	1	1