

# PHARMA DEVILS

Chatheelend bei Michien

SOP No.:	Revision No.:	00
Effective Date:	Supersedes No.	Nil
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#### 1.0 **OBJECTIVE**:

To lay down a procedure for Operation of Purified Water Circulation Loop.

#### 2.0 SCOPE:

This SOP is applicable for Operation of Purified Water Circulation Loop at .....

-p

### 3.0 RESPONSIBILITY:

Officer / Executive - Engineering

#### 4.0 ACCOUNTABILITY:

Head – Engineering

### **5.0 DEFINITION:**

**5.1 Purified water** is water that has been mechanically filtered or processed to remove impurities and make it suitable for use.

## **6.0 PROCEDURE:**

#### 6.1 PRE STARTUP CHECKS:

- 6.1.1 Check the Water Level of PW make up.
- 6.1.2 Check the Air Pressure should be 5 Kg/cm<sup>2</sup> for Pneumatic Valve Operation.

#### **6.2 OPERATION:**

- 6.2.1 Switch "ON" the Main Control of PW distribution system.
- 6.2.2 'Log in' screen shall appear, enter the user name and password.
- 6.2.3 Press the PW distribution button, the PW distribution screen shall appear.
- 6.2.4 Press the AUTO button, then the START and STOP button shall appear.
- 6.2.5 Press the START button, the PW circulation pump shall start.
- 6.2.6 Switch ON the main panel of WFI distribution system.
- 6.2.7 'Log in' screen shall appear, enter the user name and password.
- 6.2.8 Press the AUTO button, then the START and STOP button shall appear.
- 6.2.9 Press the START button, the WFI circulation pump shall start.



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6.2.10 Observe parameters mentioned in following table.

S. No.	Parameter	Range
1.	Flow Rate	NLT 7300 L/Hr
2.	Conductivity	<1.3 μS/cm
3.	Temperature (WFI)	NLT 80 Deg. C
4.	Temperature (PW)	Ambient
5.	UV Intensity	$> 9 \text{ W/m}^2$

**NOTE:** The Purified Water dump valves will be operated if the limits of conductivity & TOC are out of limit (mentioned above).

#### **6.3 VELOCITY:**

6.3.1 **Velocity** (M/Sec.) for 2" Dia Loop Line Pipe = Flow (LPH) X K /1000 Where, K = Conversion Factor (0.167)

6.3.2 **Velocity** (M/Sec.) for 1" Dia Loop Line Pipe = Flow (LPH) X K /1000 Where, K = Conversion Factor (0.802)

- **6.4** Record the Operation Details in "Purified Water Circulation Loop Operation Record" as shown in Annexure-I.
- 6.5 UV light provided in purified water circulation loop shall be replaced after 7000 burning hours.

### **7.0 ABBREVIATIONS:**

SOP Standard Operating Procedure

QA Quality Assurance

No. Number

PW Purified Water

WFI Water for Injection

UVD Ultra Violet Detector

kg Kilogram

cm Centimeter

TOC Total Organic Carbon



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## **8.0** ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Purified Water Circulation Loop Operation Record	

## 9.0 **DISTRIBUTION:**

• Controlled Copy No. 01 Head Engineering

• Master Copy Quality Assurance

## 10.0 REFERENCES:

Not Applicable

## 11.0 REVISION HISTORY:

Revision No.	Change Control No.	<b>Details of Changes</b>	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		





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## ANNEXURE - I

## PURIFIED WATER CIRCULATION LOOP OPERATION RECORD

Section: Frequency: Hourly

Date: PW- Purified Water System					- Checked By			
Time	Water level (350.1 LT-01)	Conductivity (NMT 1.3µS/cm)	Flow Rate (NLT 7300 L/Hr.)	Temperature (Ambient)	UV Intensity (> 9 W/m²)	UV Running Hours	Done By (Sign & Date)	(Sign & Date)