

PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering

Title: Sanitization of EDI System

SOP No.	Revision No.	
Effective Date	Supersedes No.	
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1.0 **OBJECTIVE:**

To lay down a procedure for Sanitization of EDI System.

2.0 SCOPE:

This SOP is applicable for Sanitization of EDI System.

3.0 RESPONSIBILITY:

Officer / Executive Engineering.

4.0 ACCOUNTABILITY

Head Engineering

5.0 PROCEDURE:

5.1 CIP SKID:

- **5.1.1** Alternate Pump shall be used for sanitization.
- **5.1.2** Fill the CIP tank with 200 lit of purified water.
- **5.1.3** Switch on the heater raise the temperature of Purified water inside the CIP Tank up to 75 °C \pm 2°C.
- **5.1.4** Circulate this hot water in EDI through circulation pump minimum for 45 min.
- **5.1.5** Drain the hot water and circulate immediately with fresh purified water, to down the temperature of the EDI System.
- **5.1.6** Officer / Executive Engineering shall intimate QC to collect the sample for the analysis.
- **5.1.7** Officer / Executive QC shall collect the sample from outlet of EDI and shall submit for analysis. After analysis QC will submits the report to QA for verification.
- **5.1.8** Officer / Executive Engineering shall prepare a Sanitization schedule as per Annexure I.
- **5.1.9** Frequency of the sanitization shall be 30 ± 7 days or whenever required.
- 5.1.10 Record the sanitization details as per Annexure –I. "EDI Sanitization Record".



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6.0 REFERENCES:

HYDROPURE Manual.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	EDI Sanitization Record	

ENCLOSURES: SOP training record

8.0 DISTRIBUTION:

Controlled Copy No. 1 Head Corporate Quality Assurance

• Controlled Copy No. 2 Head Engineering

Master Copy
Quality Assurance Department

9.0 ABBREVIATIONS:

SOP Standard Operating Procedure

QA Quality Assurance QC Quality Control °C Degree Centigrade

CQA Corporate Quality Assurance

ID Identification No.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	New SOP	Nil	Nil	Nil



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ANNEXURE – I EDI SANITIZATION RECORD

Area: Location:

Frequency: Monthly.

S.No.	Date	Temp. 75± 2°C	Water collected for sanitization (200 ltr)	After achieving temp. circulation Time (45 Min)		Done by	Checked By
				Start Time	End Time		
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							