

PHARMA DEVILS

ENGINEERING DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Engineering

Title: Sanitization of Multi Column Distillation Plant.

SOP No.	Revision No.	
Effective Date	Supersedes No.	
Review Date	Page No.	1 of 3

1.0 OBJECTIVE

The purpose of this SOP is:

1.1 The Objective of this SOP is to describe the procedure for Sanitization of Multi Column Distillation Plant.

2.0 SCOPE

This SOP is applicable for the procedure for Sanitization of Multi Column Distillation Plant.

3.0 RESPONSIBILITY:

- 3.1 The Maintenance Operator shall be responsible:
- 3.1.1 Responsible for sanitization of Multi Column Distillation plant.
- 3.1.2 Responsible for maintaining the sanitization record.
- 3.2 The Maintenance Engineer shall be responsible:
 - **3.2.1** Responsible for proper operation of the plant.
 - **3.2.2** Responsible to take corrective action if any deviation observed.

4.0 ACCOUNTABILITY

Head –Engineering Services

5.0 PROCEDURE:

5.1 PRIMARY CHECKS:

- 5.1.1 Before carrying out the sanitization, ensure that the power supply for the main power panel is OFF.
- 5.1.2 Ensure that SS flexible hose, which is used for sanitation, is flushed with purified water for 15 minutes.

5.2 STARTING PROCEDURE:

5.2.1 SANITIZATION FOR COLUMNS (STILLS):

5.2.1.1 Drain out the water from the columns by opening the drain valves.



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Review Date	Page No.	2 of 3

- **5.2.1.2** Close the drain valves.
- **5.2.1.3**Connect the pure steam supply line to the feed water inlet line of the plant with Cleaned SS flexible hose.
- **5.2.1.4** Start the pure steam generation plant ref. SOP.
- **5.2.1.5** Allow the steam to flow through columns for two hours.
- **5.2.1.6** After two hours, stop the pure steam generation plant and disconnect the SS Flexible hose.
- **5.2.1.7** Flush the plant with purified water for 30 minutes.
- **5.2.1.8** Keep the SS flexible hose properly rolled and both ends should be closed for next sanitization.

5.2.2 SANITIZATION FOR TOP COOLER (HEAT EXCHANGER):

- **5.2.2.1** Connect the pure steam line to the top cooler by using SS flexible hose.
- **5.2.2.2** Follow the same steps, which are used for column sanitation.
- **5.2.2.3** After flushing start the plant as per Ref. SOP.

5.2.3 FREQUENCY OF SANITIZATION:

5.2.3.1 Sanitization of the multi column distillation plant has to be carried out in every month. Frequency is decided on the basis of past experience), However QC will monitor the quality parameters related to microorganism and if any changes required in frequency, should be incorporated.

6.0 ANNEXURES:

ANNEXURE-I: Multi Column Distillation Plant Sanitization Record

7.0 References (S):

NIL

8.0 Glossary

SOP : Standard Operating procedure

No : Number



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Review Date	Page No.	3 of 3

ANNEXURE-I

MULTI COLUMN DISTILLATION PLANT SANITIZATION RECORD

S.No.	Date of Sanitization	Sanitization Time		Steam Temperature	Remarks	Operators Sign	Engineer Sign
		From	То	(°C)	Ttomat no	operators sign	Engineer sign