



**Title:** Replacement Policy of Component of Utility Services

<b>SOP No.:</b>		<b>Revision No.:</b>	00
<b>Effective Date:</b>		<b>Supersedes No.</b>	Nil
<b>Review Date:</b>		<b>Page No.</b>	1 of 4

**1.0 OBJECTIVE:**

To lay down a Procedure for Replacement policy of component of utility services.

**2.0 SCOPE:**

This SOP is applicable for replacement of components of utility services which covers following units at  
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- I. Water Treatment Plant
- II. Purified water generation system.
- III. Water for injection generation system
- IV. Purified steam generation plant.
- V. Air compressor
- VI. Nitrogen plant.

**3.0 RESPONSIBILITY:**

Executive/Officer- Engineering

**4.0 ACCOUNTABILITY:**

**Department Head:-**Approval, Ensure Training and Implementation of this SOP's.

**5.0 DEFINITIONS:**

NA

**6.0 PROCEDURE:**

The critical component of utility services are shown in below table with replacement policy.



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S.No.	NAME OF COMPONENT	REPLACEMENT POLICY
1.0	Softener Resin	When output decreases gradually.
2.0	5 Micron Filter	If found choked by showing higher pressure on pressure gauge.
3.0	RO Membrane	When output conductivity increases gradually.
4.0	EDI	When output conductivity increases gradually.
5.0	Ultra Filter	When flow rate decreases continuously.
6.0	Vent Filter	When fails in integrity test.
7.0	UV Light	When burning hours completed or show low level of UV intensity.
8.0	AHU Filter	If found choked or damage.
9.0	HEPA Filter	When it fails during validation, integrity test, velocity and other damages observed.
10.0	Air Line Filter	If found choked or damage.
11.0	Air Suction Filter	If found choked or damage.
12.0	Oxygen Sensor	When observed malfunctions

6.1 After replacement of component it should be documented as per Annexure-I.

6.2 After replacement of any component it should be discarded in scrap yard in the presence of QA.

## 7.0 ABBREVIATIONS:

No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
EN	Engineering

## 8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Replacement Record of Component of Utility Services	



# PHARMA DEVILS

ENGINEERING DEPARTMENT

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## 9.0 DISTRIBUTION:

- Master Copy                                  Quality Assurance Department.
- Controlled Copy No. 01      Engineering Department.

## 10.0 REFERENCES:

In-House

## 11.0 REVISION HISTORY:

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

