



# PHARMA DEVILS

ENGINEERING DEPARTMENT

**Title:** Sampling Procedure for Purified Water and Raw Water

<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 3

## 1.0 OBJECTIVE

To lay down the sampling procedure for purified water and raw water.

## 2.0 SCOPE

This procedure applies to the Quality Control Laboratory.

## 3.0 RESPONSIBILITY

Chemist- Quality Control  
Officer- Quality Control

## 4.0 ACCOUNTABILITY

Head - Quality Control

## 5.0 REFERENCE(S)

In- house

## 6.0 PROCEDURE

- 6.1 The sampling points shall be first identified.
- 6.2 Sample bottle shall be sterilized at 121°C for 30 minutes for microbiological analysis.
- 6.3 Before drawing the sample, sanitize the sampling point by spraying 70% IPA, wear sterile gloves and allow a steady stream of water to flow out for about 2 minutes and regulate to obtain uniform flow.
- 6.4 Sample for chemical analysis and samples for microbial testing (Aseptic sampling) to be collected separately.
- 6.5 The sampling flask and bottles are washed three times with the actual water before sampling for chemical analysis (Approx. 500 ml in shed dried Glass bottle).
- 6.6 For microbial analysis approximate 500 ml in dried, sterilized Glass bottle.
- 6.7 Collect the sample directly into sterilized sample bottle taking care to avoid contact of the mouth of the sample bottle onto any part of water outlet sampling point.
- 6.8 Fill up the bottles to full volume and cap it tightly with the sterilized closure.
- 6.9 The sample shall be taken for microbiological & chemical analysis as per sampling schedule as per Annexure I.
- 6.10 In case of extended storage, store the sample at a temperature of 4 - 8°C in the refrigerator, but Testing (except microbiological) shall be done within 4 hours.
- 6.11 The trend data for purified water points those are analyzed daily shall be prepared after every month and purified water points those are analyzed weekly shall be prepared after every three Months.

## 7.0 HISTORY



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Details are given below.

SOP No.	REASON FOR CHANGE	EFFECTIVE DATE

**8.0 ABBREVIATIONS:** The abbreviations used in the SOP are:

- SOP - Standard Operating Procedure
- No. - Number
- QA - Quality Assurance
- QC - Quality Control



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**ANNEXURE – I**

**LIST OF PURIFIED WATER SAMPLING POINT**

<b>S.No.</b>	<b>DESCRIPTION OF SAMPLING POINT</b>	<b>SAMPLING POINT</b>	<b>REMARKS</b>
1.	Bore Well		
2.	Mixed Bed		
3.	After UV		
4.	After Storage Tank		
5.	After Ultra filtration		
6.	After Storage (Purified Water)Tank		
7.	After UV		
8.	Auto coater		
9.	Wash Room		
10.	Blending Area		
11.	Wash Room		
12.	Granulation Area		
13.	Wash Room		
14.	Instrument Room		