



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Quality Monitoring of Water

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
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1. **Purpose:** The purpose of this SOP is to describe the procedure for Quality Monitoring of Water.
2. **Scope:** This SOP is applicable to Purified Water and Potable Water.
3. **References, Attachments & Annexures:**
 - 3.1 **References:**
 - 3.1.1 Indian Pharmacopoeia
 - 3.1.2 British Pharmacopoeia
 - 3.1.3 In- House
 - 3.1.4 SOP for Issuance and writing of analytical raw data in template/protocol
 - 3.2 **Attachments:**
 - 3.2.1 Attachment-1: Monthly Water Sampling Schedule
 - 3.2.2 Attachment-2: Label For Sampling Details
 - 3.2.3 Attachment-3: Format for the Intimation of out of limit results of microbial analysis of water .
 - 3.3 **Annexure:**
 - 3.3.1 Annexure-1: List of sampling points of Purified and Potable Water.
4. **Responsibilities:**
 - 4.1 **Microbiologist:**
 - 4.1.1 To perform the activity as per SOP.
 - 4.1.2 To maintain all the records as per SOP.
 - 4.2 **QC Head or designee:**
 - 4.2.1 To check the SOP.
 - 4.2.2 To give training to all concerned persons before implementation of SOP.
 - 4.3 **Quality Assurance:**
 - 4.3.1 To check the SOP.
 - 4.3.2 To ensure the implementation of system as per SOP.
 - 4.4 **Regulatory Affairs, Quality Head & Plant Head:**
 - 4.4.1 To review and approve the SOP.
5. **Distribution:**
 - 5.1 Quality Assurance Department.



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5.2 Microbiology Section.

6. Abbreviations & Definition of Terms:

6.1 Abbreviations

- 6.1.1 **PW:** Purified Water.
- 6.1.2 **MLT:** Microbiological Limit Test
- 6.1.3 **LIMS:** Laboratory Information Management System.
- 6.1.4 **SOP:** Standard Operating Procedure
- 6.1.5 **PT:** Potable Water
- 6.1.6 **IP :** Indian Pharmacopoeia.
- 6.1.7 **BP:** British Pharmacopoeia.
- 6.1.8 **STP :** Standard Testing Procedure
- 6.1.9 **A.R. No.:** Analytical report number
- 6.1.10 **IPA** : Iso propyl alcohol
- 6.1.11 **COA** : Certificate of analysis

6.2 Definition of Terms

- 6.2.1 **Alert limit:** Microbial levels, specified in the standard operating procedure or specifications, when exceeded should result in an investigation to ensure that the process is still within control. Alert levels are specific for a given facility and are established on the basis of a baseline developed under an activity monitoring program. These Alert levels can be modified depending on the trend analysis done in the monitoring program. Alert levels are always lower than Action levels.

7. Procedure:

- 7.1 **Preparation of monthly sampling schedule:** Refer Attachment 1,2,and 3 for the preparation of monthly sampling schedule.
- 7.2 **Frequency for sampling and analysis:**
 - 7.2.1 **Purified water user points and Storage tank:** Each point shall be analyzed for chemical and microbiological tests once in a month.
 - 7.2.2 Purified water from supply loop (PW01) and return loop(PW 51) samples shall be analyzed daily for chemical and microbiological tests.
 - 7.2.3 After mix bed water (PW 49) sample shall be analyzed for description, pH and conductivity tests and released daily basis for the further use.
 - 7.2.4 **Potable water sample :**All points including tank shall be analyzed **once in three month.** Samples shall be analyzed for chemical and microbiological tests. Storage tank sample shall be analyzed on daily basis for chemical and microbiological tests.
- 7.3 **Issuance of water analysis template**



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- 7.3.1 Before analysis, sample shall be registered and template shall be generated from LIMS.
- 7.3.2 A designated person shall issue the template and make necessary entries for the same as per SOP.
- 7.3.3 Follow the protocol issuance number as per SOP.
- 7.4 **Sampling Procedure:**
- 7.4.1 Collect the sample from the sampling point as mention in the schedule.
- 7.4.2 Before sampling sterilized the sampling containers for microbiology test at 121⁰ c/15 lb. for 15 min.
- 7.4.3 Sample container shall be having details as per attachment- 2. Where
- 7.4.3.1 **Sampling Point Type:** In this mention which type of water to be sampled as per water sampling schedule such as Purified /Potable.
- 7.4.3.2 **Sampling Point Location:** Mention the sampling point location name where to be sampled, such as Quality Control.
- 7.4.3.3 **Sampling ID No.:** Mention the sampling ID no. such as PW 48.
- 7.4.3.4. **Sampled By :** Name and Sign. of person which perform the sampling.
- 7.4.3.5 **Date and Time:** Mention the date and time of sampling.
- 7.4.4 A person trained in water sampling shall collect the samples from sampling points.
- 7.4.5 Sanitized the hand with 70% IPA and wear cap, nose mask and hand gloves.
- 7.4.6 Before collecting the sample drain out the water from sampling point for 30 second with full valve open.
- 7.4.7 Sample shall be collected in a manner that the water sample should be overflow from the sample bottle and immediately closed with stopper.
- 7.5 **Tests, acceptance criteria and testing method:**
- 7.5.1 **For Purified Water and Potable Water Samples:**
- 7.5.1.1 Carry out the testing as per Standard Testing Procedure of Purified water.
- 7.5.1.2 Carry out the testing as per Standard Testing Procedure of Potable water.
- 7.5.2 Factory specification and template should be generated from LIMS which shall be approved by Quality Head and retained as master documents
- 7.6 **Hold time for sample analysis**
- 7.6.1 Samples shall be analyzed as soon as possible after being collected. If it is not possible to test the sample within about 2 hrs of collection, the sample should be held at refrigerated temperatures (2-8°C) for maximum of 12 hrs to maintain the microbial attributes until analysis.
- 7.7 **Recording of Results:**
- 7.7.1 Record the procedure followed, raw data and results in the template, and results in COA.



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7.7.2 Details required to generate analytical report shall be entered in LIMS.

7.7.3 After completion of analysis get the protocol and analytical report checked and approved by designated person.

7.8 Acceptance Criteria:

7.8.1 Refer current Specification for acceptance criteria of purified water.

7.8.2 Refer current Specification for acceptance criteria of potable water.

7.9 A.R. Numbering System:

7.9.1 Give A.R. No. of purified water, potable water and raw water using subsequent prefix code PW and PT then point no.(xx), then last two digit of year (yy) and four digit serial number. For example, if first purified water is analyzed then A.R. No. shall be PWXX130001. For giving A.R. No. to potable follow same A.R. numbering system except prefix code.

7.10 Release Procedure:

7.10.1 After mix bed water:

7.10.1.1 Engineering shall be informed for release status of purified water sample collected after mix bed through the format.

7.10.2 Potable water:

7.10.2.1 Potable water shall be released after ensuring proper documentation. Engineering and production shall be informed only if any failure is noticed.

7.11 Handling of out of specification results

7.11.1 Chemical

7.11.1.1 If the sample exceeds specified limit for chemical test, manufacturing and QC Head shall be informed immediately for initial failure. Reanalysis of the same sample shall be done. If fails in reanalysis, than re-sampling and re-testing shall be done. If re-sample passes, investigation shall be done for initial failure and document the same.

7.11.1.2 If the re-sample exceeds specified limit for any of the parameter, Quality Head, engineering, production and QA shall be informed for necessary investigation and action.

7.11.1.3 Necessary record for repeat analysis and /re-sample analysis shall be maintained.

7.11.2 Microbiological (Purified water): Alert limit -36 cfu/ml

7.11.2.1 For any of the samples, if results exceed the alert limit, Quality Head, QA, Production and Engineering shall be informed as per Attachment No.-3

7.11.2.2 Cause for the out of limit results shall be investigated in consultation with QA. For example,

7.11.2.2.1 Evaluation of sanitization record of PW system.



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7.11.2.2.2 Evaluation of usage of the particular sampling point.

7.11.2.2.3 Review of the results of other samples collected on the same day.

7.11.2.3 Based on the above investigation, corrective actions shall be planned.

7.11.2.4 Based on the above investigation and corrective actions, decision shall be taken for additional quality monitoring of the particular sampling point

7.11.3 **Microbiological (Purified water) : limit-100 cfu/ml**

7.11.4 Investigation report

7.11.4.1 Investigation report can be prepared as per incidence investigation procedure.

7.12 Trending

7.12.1 Purified water quality parameter trending shall be done on monthly basis, trend charts shall be reviewed and conclusion shall be made.

7.12.2 Potable/ Process water trending shall be done quarterly (every three months).

7.13 Identification of microorganisms (Water Isolates):

7.13.1 Water isolates shall be identified due to following reasons.

7.13.1.1 Identifying the isolates recovered from water monitoring methods may be important in instances where specific water borne microorganisms may be detrimental to the products or processes in which the water is used.

7.13.1.2 Often a limited group of microorganisms is routinely recovered from a water system. After repeated recovery and characterization, an experienced microbiologist may become proficient at their identification based on only a few recognizable traits such as colonial morphology and staining characteristics. This may allow for a reduction in the number of identifications to representative colony types, or, with proper analyst qualification, may even allow testing short cuts to be taken for these microbial identifications



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Attachment-2 Label For Sampling Details

Sampling Details

Sample Point Type:
Sampling Point Location:
Sample ID No. :
Sampled By:
Date and Time :



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Attachment-3

Format for the Intimation of out of limit results of microbial analysis of water

From : Micro Lab			To : Engineering		
Date :			CC: Production QA		
Type of water (Potable/Purified)	Sample ID/ Sampling point	Date of Sampling	Microbial Analysis Results	Limit	
				Alert Limit	Action Limit

Prepared by:
Date

Authorized by :
Date

Intimation Received by -
Engineering (Sign/Date) :
Production Head (Sign/Date) :
Quality Assurance (Sign/Date) :

