



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Recording and Review of Analytical Results in Microbiology Section

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 4

1. **Purpose:** The purpose of this SOP is to describe the procedure for receipt, analysis and reporting of samples in Microbiological section.
2. **Scope:** This procedure is applicable for the microbiology laboratory.
3. **References, Attachments & Annexures:**
 - 3.1. **References:**
 - 3.1.1. In – house
 - 3.1.2. SOP Microbiological analysis of in process samples and finished products
 - 3.2. **Attachments:**
 - 3.2.1. Attachment 1: Sampling and Analysis Register For Water
 - 3.2.2. Attachment 2: Cleaning and disinfectant Solution Preparation Record
 - 3.3. **Annexures:** None
4. **Responsibilities:**
 - 4.1. **Microbiologist:**
 - 4.1.1. To perform the activity as per SOP.
 - 4.1.2. To maintain the records as per SOP.
 - 4.2. **QC Head or designee:**
 - 4.2.1. To check the SOP.
 - 4.2.2. To give the training to all concern persons.
 - 4.3. **Quality Assurance:**
 - 4.3.1. To check the SOP
 - 4.3.2. To ensure proper implementation of SOP.
 - 4.4. **Regulatory Affairs, Quality Head , Plant Head:**
 - 4.4.1. To review and approve the SOP.
5. **Distribution:**
 - 5.1.1. Quality Assurance
 - 5.1.2. Quality control (Microbiology Section)
6. **Abbreviations & Definition of Terms:**
 - 6.1. **Abbreviations:**



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6.1.1. SOP: Standard Operating Procedure

6.1.2. TVC: Total viable count

6.1.3. v/v : Volume /volume

6.2. **Definition of Terms:** None

7. Procedure:

7.1. Procedure for Finished products and raw materials.

7.1.1. Upon receipt of samples requisition from Quality Assurance and Raw material section, the entry shall be made in the register of “ Microbial limit test Log-book.” as per SOP.

7.2. Procedure for receipt, analysis and reporting of samples of water.

7.2.1. As per water sampling schedule water sampled from different sampling points for routine analysis, the samples shall be collected by the microbiologist from these points and the details shall be entered in sampling and analysis register for water as per attachment-1

7.2.2. The results of tests shall be recorded in the work sheet for the analysis of Raw material / Finished products or protocol note book / register for other work i.e. Validations, water analysis and the reporting of the tests shall be made on microbiological tests report formats, and shall be checked and signed by the microbiologist and designee after reviewing for correctness and completeness.

7.2.3. The analysis of the sample shall be carried out as per the test procedures and specifications.

7.2.4. Record the cleaning and disinfectant solution preparation record for microbiology section as per Attachment –2.



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Cleaning and disinfectant Solution Preparation Record

S. No	Date of preparation	Name of Solution	Concentration % v/v	Volume prepared	Prepared by	Checked by

8. History

Version No.		Effective Date	