



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Responsibility of Microbiologist

SOP No.:		Department:	Microbiology	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 2	

1. **Purpose:** The purpose of this SOP(Standard operating procedure)is to define the procedure for the Responsibilities of Microbiologist of Quality Control Unit.
2. **Scope:**This procedure is define the responsibilities of all personnel working in microbiology section.
3. **References, Attachments & Annexures:**
 - 3.1. **References:**
 - 3.1.1. In-house
 - 3.2. **Attachments:** None
 - 3.3. **Annexures:** None
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.
 - 4.2.3. To maintain the record suggested in the 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. **Distributions:**
 - 5.1. Microbiology
 - 5.2. Quality Assurance
6. **Definitions of terms & Abbreviations:**



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6.1. **Definitions of terms:**None

6.2. **Abbreviations:**

6.2.1. **SOP** :Standard Operating Procedure

6.2.2. **No.** : Number

6.2.3. **QA** :Quality Assurance

6.2.4. **QC** :Quality Control

6.2.5. **NA** : Not Applicable

7. Procedure:

7.1. **General:**

7.1.1. To carry out the Microbiological analysis of raw materials including its documentation.

7.1.2. To carry out the microbiological analysis of purified water and potable water including its documentation.

7.1.3. To carry out the microbiological analysis of finished products including its documentation.

7.1.4. To maintain the cleanliness of microbiology laboratory.

7.1.5. To perform the environmental monitoring.

7.1.6. To calibrate the microbiological instruments.

7.1.7. To maintain the microbiological cultures.

7.1.8. To prepare and sterilize the media for microbiological analysis and its documentation.

7.2. **Laboratory attendant/helpers**

7.2.1. To clean and maintain the cleanliness of laboratory premises.

7.2.2. To wash used glasswares.

8. History:

Version No.		Effective Date	