



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Responsibility of Microbiologist	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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 rresponsibilities 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:**
 - 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



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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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:

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