



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Analyst Qualification	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Analyst qualification working in the Microbiology laboratory.

2.0 SCOPE:

This SOP is applicable for qualifying all newly recruited Analysts and existing Analysts working in Microbiology lab.

3.0 RESPONSIBILITY:

Microbiologist to undergo Analyst Qualification.

Section head- Microbiology department

Head- Quality control

4.0 PROCEDURE:

4.1 To Qualify a Microbiologist, the Head Quality control or the designee shall ensure that the microbiologist has been trained in the tests.

4.2 Analyst need not be qualified on below instruments/Equipment like pH meter, hot air oven water bath, colony counter, microscope, zone reader, incubator etc.

4.3 The sample should be allotted to the microbiologist to be qualified by the qualified Microbiologist.

4.4 The analyst shall be qualified for the following tests:

- i) Microbial Limit Test of Raw material.
- ii) Microbial Limit Test of Finished Product.
- iii) Antibiotic Assay
- iv) Water Analysis.

The microbiologist shall also be given training to operate different equipment used in microbiology lab.

4.5 Microbiologist shall perform the test in triplicate as per the Standard test procedure under the supervision of section Head and report the results in the analytical raw data sheet as per



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Annexure-III.

4.6 Microbiologist shall record the results in respective Analytical data sheet/ Report/Format and submit the Report to the Section head or designee for checking.

S.No.	Test	Acceptance Criteria
1	Microbial Limit Test	Should comply with the specification
2	Antibiotic Assay	Should comply with the specification
3	Water Analysis	Should comply with the specification

4.7 In case analyst failed to meet the acceptance criteria on allotted sample, Analyst shall be retrained under the strict supervision of section head or his designee and requalify in respective test.

4.8 The Analyst Qualification Log book shall be maintained for every Microbiologist as per Annexure-I.

4.9 An analyst qualification Matrix shall be prepared for every Microbiologist that contains the list of tests as per Annexure-II. The qualification record of analyst should be recorded in Annexure-III and evaluation of microbiologist should be done as per Annexure-IV.

5.0 ANNEXURE (S):

Annexure-I: Analyst qualification log book

Annexure-II: Analyst qualification matrix

Annexure-III: Qualification record of analyst

Annexure-IV: Analyst evaluation sheet

6.0 REFERENCE (S):

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

Nil



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	----	New SOP	----