PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Analytical Method Validation of Microbiological Test	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Analytical Method Validation of Microbiological test.

2.0 SCOPE:

This SOP is applicable for Analytical Method Validation of Microbiological test i.e. Microbial limit test, Sterility test, Bacterial Endotoxin test and bioassayin Microbiology Lab of Quality Control Department.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiology

4.0 ACCOUNTABILITY:

Head – QC, Head QA

5.0 ABBREVIATIONS:

Ltd.	Limited
No.	Number
QC	Quality Control
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 Analytical Method Validation is the collection of documented evidence that an Analytical Procedure is suitable for its intended use.

6.2 Analytical Method Validation for Microbiological testing shell be prepare as per SOP "TitledPreparation, Review, Approval, Authorization, Control, Execution, Compilation, Revision of Validation / Qualification Protocols and Reports.

6.3 Role and Responsibility of Analytical Method Validation for Microbiological testing as given below Table.

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DEPARTMENTS	RESPONSIBILITIES
Officer /Executive Microbiologist	• To Prepare Analytical Method Validation Protocol & Report. • Shall compile the Analytical Method Validation Report.
Operating Manager Microbiology	• Review, Training and effective implementation of the Analytical Method Validation Protocol & Report • To monitor all Validation Activities and ensuring the Validation are carried out as per the Protocol
Quality Assurance	• Sample shall be provided for analytical method validation. • To Review and Approval of Protocol & Report • To monitor Protocol completeness and Technical Accuracy. • Post approval of Validation Report after execution.

6.4 The most common Analytical Method Validation for Microbiological test is as follows:

- Microbial Limit test
- Sterility test
- Bacterial Endotoxin test
- Bioassay

6.5 Protocol shall be prepared to performed Analytical method validation of microbiological test i.e. Microbial limit test, Sterility test, Bacterial Endotoxin test and bioassay.

6.6 Validation protocol shall describe the procedure for the validation.

6.7 If any product have multiple strength; analytical method validation shall be performed on higher strength considering as worst caseand same method validation shall be applicable for lower strength also.

e.g. Product have two composition like Olmesartanmedoxomil 40+Amlodipine 5 + Hydrochlorthiazide 12.5mg Tablets and Olmesartanmedoxomil 20+Amlodipine 5 + Hydrochlorthiazide 12.5mg Tablets.

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MLT method validation shall be performed on higher strength (Olmesartan medoxomil 40+Amlodipine 5 + Hydrochlorthiazide 12.5mg Tablets) considering as worst case and same method validation shall be applicable for lower strength (Olmesartan medoxomil 20+Amlodipine 5 + Hydrochlorthiazide 12.5mg Tablets) also.

6.8 Three different batches of the productor as per customer requirement shall be required for Analytical Method Validation.

6.9 Sample for analytical method validationshall be provided by QualityAssurance.

6.10 All the personnel involved in the Analytical Method Validation shall be appropriately trained both in their job related activities and on the Method Validation Protocol by Head-Microbiology or his/her designee.

6.11 Verify the Training Records of the persons involved in the Validation and record the details in Analytical Method Validation Report.

6.12 Ensure all instruments to be used in Method Validation must be calibrated. Thereference Calibration Documents shall be verified and mentioned in Analytical Method Validation Report.

6.13 Culture medium, reference strains of micro-organisms shall be ensure before initiation of Analytical Method Validation.

6.14 Details of Equipment and instrument to be used in method validation shall be verified and mentioned in Method Validation Report

6.15 Critical control parameters shall be identified and it should be considered and recorded. Following are the common critical points-

- Medium should be complies for GPT test.
- Incubators should be qualified.
- Autoclave should be qualified.
- The magnehalic gauge reading, temperature and Humidity reading of the testing area shall observe before proceeding for validation operations.

7.0 ANNEXURES:

Not Applicable.

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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 — Quality Assurance
- Controlled Copy No. 02 — Microbiology
- Master Copy — Quality Assurance

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By