



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Procedure for Microbiological Assay Test	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Microbiological Assay Test.

2.0 SCOPE:

This SOP is applicable for analysis of Vitamins, Antibiotics and probiotic in process validation, in-process samples, finished product, semi-finished product and stability study samples in Microbiology Section.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiology

4.0 ACCOUNTABILITY:

Head QC

5.0 ABBREVIATION:

Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
S.No.	Serial Number

6.0 PROCEDURE:

6.1 Prerequisite for Microbiological Assay Test

S.No.	Requirements
1.	Spatula
2.	Calibrated Analytical Balance
3.	Pre Sterilized Empty Petriplate
4.	Calibrated Micropipette (20-200 µl, 100-1000 µl)
5.	Sterilized Micropipette Tips 20-200 Micro litre & 100-1000 Micro litre
6.	Sterilized Test Tube-10ml, 20 ml
7.	Vortex
8.	Butter paper
9.	Sterile Borer



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S.No.	Requirements
10.	Vernier Caliper
11.	Volumetric flask 20 ml, 50ml 100 ml
12.	Pipette (1 ml, 2ml, 5ml and 10 ml)
13.	Sterile saline solution
14.	70% IPA filtered with 0.22 μ
15.	Sterile lint Free Cloth
16.	Infrared Gun
17.	Culture media

- 6.2** After receiving the samples for microbiological assay test, record the details of samples in sample receiving record e. g. S.No. Date of receipt, Product Name, Batch No., Sample quantity, A.R.No. etc. in **Annexure-I**, Titled “**Sample Receipt/Analysis Record for Microbiological Assay Test**” Format.
- 6.3** Microbiological Assay Test shall be performed as per below mentioned documents:
- 6.3.1 Raw materials or Bulk Sample:** As per specification and standard testing procedure.
 - 6.3.2 Semi-finished and Finished Product:** As per specification and standard testing procedure.
 - 6.3.3 In Process Sample:** As per standard testing procedure.
 - 6.3.4 Hold Time Study :** As per standard testing procedure.
 - 6.3.5 Process Validation:** As per standard testing procedure.
- 6.4 PRECAUTION:**
- 6.4.1** Use amber color glassware for sample and standard preparation in light sensitive product.
 - 6.4.2** Ensure the temperature of media cool approximate 45°C before inoculating culture suspension.
 - 6.4.3** Always use Bio-safety cabinet for culture preparation.
 - 6.4.4** During analysis avoid excess light in area for light sensitive product.
 - 6.4.5** Carefully transfer the assay plates in incubator.
 - 6.4.6** Glassware’s shall be calibrated.
 - 6.4.7** Weighing shall be done carefully with calibrated analytical balance.
 - 6.4.8** Use safety precautions during test as when required.
 - 6.4.9** All activity should be recorded in logbook.



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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sample Receipt/Analysis Record For Microbiological Assay Test	

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

