PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Microbiological analysis of In-process samples and finished products

SOP No.:		**Department:**	Microbiology
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	1 of 5

1. **Purpose:** The purpose of this SOP is to define a procedure for Microbiological analysis of in process samples and finished products.

2. **Scope:** This SOP is applicable for microbiological analysis of In process samples and Finished products in Quality Control department.

3. **References, Attachments & Annexures:**
   - 3.1 **References:**
     - 3.1.1 Inhouse.
     - 3.1.2 SOP No. : Issuance and writing of analytical raw data in template /protocol.
     - 3.1.3 SOP No. :Approval & rejection of material through ERP system.
     - 3.1.4 SOP No.:Receipt,storage,preparation and growth promotion test,used and disposal of microbiological media.
     - 3.1.5 SOP No.:Washing and cleaning procedure for glassware in microbiology laboratory.
     - 3.1.6 SOP No.:Procedure for procurement,transfer,preservation and disposal of microbiological culture.
     - 3.1.7 SOP No.:Handling of out of specification results for micrbiological analysis.
   - 3.2 **Attachments:**
     - 3.2.1 Attachment – I : Microbiological limit test Log book
   - 3.3 **Annexures:** None

4. **Responsibility:**
   - 4.1 **Microbiologist:**
     - 4.1.1 To perform the activity as per SOP.
     - 4.1.2 To maintain the records as per SOP.
   - 4.2 **QC Head or designee:**
     - 4.2.1 To check the SOP.

4.2.2 To give the training to all concern persons.

4.3 **Quality Assurance:**

4.3.1 To check the SOP.

4.3.2 To ensure proper implementation of SOP.

4.4 **Regulatory Affairs, Quality Head , Plant Head:**

4.4.1 To review and approve the SOP.

5. **Distribution:**

5.1 Quality Assurance

5.2 Quality Control (Microbiology)

6. **Abbreviations & Definitions of Terms:**

6.1 **Abbreviations:**

6.1.1 MLT : Microbiological limit test.

6.1.2 TAMC : Total aerobic microbial count.

6.1.3 TYMC: Total combined mould and yeast count.

6.1.4 QA : Quality Assurance.

6.1.5 QC : Quality control.

6.1.6 SOP : Standard Operating Procedure.

6.1.7 LIMS : Laboratory information management system

6.1.8 ATP : Analytical testing procedure

6.2 **Definitions of Terms**

6.2.1 **Colony :** A colony is a pile or mass of a sufficiently large number of cells growing on or in solid medium that they are visible to the naked eye.

6.2.2 **Colony forming unit (CFU):** Visible outcome of growth of micro-organisms arising from a single or multiple cells.

6.2.3 **MLT:** Microbiological limit test shall include following sub tests.

6.2.3.1 TAMC: Total aerobic microbial count.

6.2.3.2 TYMC: Total combined mould and yeast count.

6.2.3.3 Test for specified micro organisms (i.e. Test for Salmonella species and E.coli and Test for S.aureus and Ps. Aeruginosa.).

7. **Procedure:**

7.1 **General :**

7.1.1 For issuance and writing of analytical raw data in template/protocol for finished products, refer SOP.

7.1.2 The microbial limit test should be carried out under condition design to avoid accidental contamination during the testing.

7.2 **Microbial limit test of in process and finished products :**

7.2.1 **Frequency:**

7.2.1.1 Microbiological analysis shall be performed for batches and /or validation batches (as per respective specification and ATP).

7.2.1.2 After review of the microbiological analysis data of these batches if the data found satisfactory then the microbiological analysis shall be performed for one in ten batches for each finished product.

7.2.1.3 For domestic products the MLT shall not be part of release specification.

7.2.1.4 Any product, if it is exported as per the requirement, the specification will be checked for microbiological tests and analysis will be performed for those batches.

7.2.1.5 Any major changes in the formulation shall be reviewed and if required, microbiological analysis will be done for those batches.

7.2.1.6 For export products MLT shall be part of release specification if required (i.e.as per requirement or registration in respective country).

7.2.2 **Sampling and Test procedure:**

7.2.2.1 Product before packing shall be sampled as finished drug product.

7.2.2.2 Perform the microbiological analysis of In process sample and Finished product as per respective specification and analytical testing procedure(ATP).

7.2.2.3 The test details and results shall be recorded in respective templates and LIMS.

7.2.2.4 Analyst shall handover the completed report to section head or designee for its checking.

7.2.2.5 Section head or designee shall review the report as per respective specification and ATP.

7.2.2.6 If results complies as per respective specification then release the batch

7.2.2.7 If results do not comply as per respective specification then inform to department head and proceed for further investigation as per respective SOP **"**Handling of out of specification results for micrbiological analysis"

7.2.3 **Acceptance criteria (limit):** As per respective specification.

Attachment – 1

Microbiological limit test Log book

Date of analysis	Product/Material Name	B.No	No. of cfu/plate (TBC)	Avg.No. of cfu	No. of cfu/plate (TYMC)	Avg.No. of cfu

Test for pathogens				Release date	A. R. No	Analysed By	Checked By	Remark
E. coli	S. aureus	Salmonella	Ps. aeruginosa					

8. **History:**

Version No.		Effective Date	