STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Microbial Limit Test of Water, Non-Sterile Product & Material	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down the Harmonized procedures for enumeration of Total aerobic Microbial count, total combined yeast and mould count and microbiological examination of specified microorganisms for Water, Raw material, In Process and finished product & stability sample.

2.0 SCOPE:

This procedure applies to carry out total aerobic microbial counts, total combined yeast and mould counts and microbiological examination of specified microorganisms for Water, Raw material, intermediates and finished product & stability sample.

3.0 RESPONSIBILITY:

Q.C- Microbiologist.

Head -Quality Control.

4.0 PROCEDURE:

4.1 **For Water:** Refers SOP for Microbiological Enumeration method.

For Non Sterile Product / Material: Refer GTP for Total Aerobic Microbial Count As per Harmonized and IP method.

4.2 Record the result for water in Annexure-II and For Non sterile Product / Material in Annexure-III.

4.3 **For Microbiological Examination of Specified Micro-Organisms:**

4.4 Refer GTP Test for Specified Microorganisms As per Harmonized and IP method.

Examined Sample should be free from following specified microorganisms as below:

1) Escherichia coli.

2) Salmonella spp.

3) Staphylococcus aureus.

4) Pseudomonas aeruginosa.

5) Shigella boydii

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6)Bile tolerant Gram negative bacteria

7)Candida albicans

8)Clostridium Sporogenes

9) Or As per individual monographs

4.5 For investigation of any out of specification test result follow the SOP.

5.0 ANNEXURE (S):

Annexure –I: Sample Inward register for Microbiological Examination of Non- Sterile product / material

Annexure-II: Analytical Test Report for Microbiological examination of Water.

Annexure- III: Analytical Test Report for Microbiological examination of Non-Sterile Products / Material.

6.0 REFERENCE (S):

- Test for Total Aerobic Microbial Count As Per Harmonized and IP Method.
- Test for Specified Microorganisms As Per Harmonized and IP Method.
- Pharmacopoeia: As per current version of IP, BP, USP and European Pharmacopoeia.
- Investigation of out of specification of test results in microbiology.
- Sampling, Testing, Release & Rejection of Water.
- Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S):

GTP: General test procedure.

SOP: Standard Operating Procedures

Q.C.: Quality control.

QCM: Quality Control Micro.

IP: Indian Pharmacopoeia

BP :British Pharmacopoeia

USP: United States Pharmacopoeia

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EP: European Pharmacopoeia

TAMC : Total Viable Aerobic Microbial Count (TAMC)

TYMC : Total Yeast and Mould Count (TYMC)

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.