STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Calibration Of Walk-In- Incubators 20-25°C and 30-35°C	**Effective Date:**
Supersedes: Nil	**Review Date:**
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PURPOSE:

The purpose of this SOP is to lay down a procedure for the microbiological monitoring of raw material and finished products.

SCOPE:

This SOP describes the procedure to check the bioburden level of finished products and raw materials in Microbiology laboratory located at .....

RESPONSIBILITY:

Officer/Executive - Quality Control.

ACCOUNTABILITY:

Head –QC department.

PROCEDURE:

1.0 Frequency:

1.1 For Raw materials – As per the Raw material specification.

1.2 For finished product / stability samples: First three batches of validation/ batches subjected to validation, then every tenth batch and all batches manufactured for export purpose.

2.0 Make entry of raw materials, finished products/stability samples in Microbial limit test (MLT) log book as per Annexure II.

3.0 Raw material are tested for total aerobic microbial counts, Yeast/mould counts and pathogens as per the specification and results are recorded in Annexure -I.

4.0 The acceptance criteria for the raw materials are specified individually as per the specification limit.

5.0 MLT of finished product (FP) is carried out as per requirement of FP specification.

6.0 MLT of FP samples which are not mentioned in specification is carried out as per In-house procedure according to their frequency.

6.1 The acceptance criteria for the finished products(Non sterile dosage forms) are:

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S.No.	Route of administration	Total Aerobic Microbial count (TAMC) (Cfu/g or Cfu/mL)	Total Yeast & Mold count (TYMC) (Cfu/g or Cfu/mL)	Specified micro-organisms (1g or 1mL)
1.	Non-aqueous preparation for oral use	10^3	10^2	Absence of *E.coli*, *Salmonella*, *P.aeruginosa* and *S.aureus*
2.	Aqueous preparation for oral use	10^3	10^2	
3.	Vaginal use	10^3	10^2	
4.	Topical use	10^2		

7.0 When results exceed acceptance limits, investigation on water analysis and environmental monitoring is carried out. Cleaning and sanitization in the manufacturing area is intensified.

8.0 ANNEXURE(S):

Annexure I**:** Microbiological Limit Test Report.
Annexure II**:** Microbial Limit Test Log Book.
Annexure III**:** Bioburden Monitoring of Raw Material and Finished products
(Test Report for Total aerobic microbial count and pathogens testing as per USP.)
Annexure IV**:** Bioburden Monitoring of Raw Material and Finished products.
(Test Report for Total aerobic microbial count and pathogens testing as per BP.)
Annexure V**:** Hold Time / Cleaning Validation Log Book.
Annexure VI**:** Microbiological Assay Log Book.
Annexure VII**:** Microbiological test report for Rinse Sample
Annexure VIII**:** Microbiological test report for Swab Sample
Annexure IX**:** Bioburden Monitoring of Raw Material and Finished products (Test Report for Total viable aerobic count and specified micro-organisms testing as per IP.)

9.0 REFERENCE(S):

USP, BP and IP Pharmacopeia's.

Revision No.	Effective Date	Reason for review	Signature & Date	Remarks