PROTOCOL FOR REVIEW OF PROCESSES FOR MICROBIOLOGICAL TESTING

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1.0 PRE- APPROVAL:

This protocol for review processes for Microbiological testing, have been checked and approved by the following functional heads.

Protocol prepared by:

Designation	Name	Sign	Date
Executive- Quality Assurance			

Protocol checked by:

Designation	Name	Sign	Date
Head Quality Control			
Dy. Manager- Quality Assurance			

Protocol approved by:

Designation	Name	Sign	Date
Head Quality Assurance			

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2.0 TABLE OF CONTENTS:

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3.0 PURPOSE:

This protocol has been designed for review of Data and procedure for Microbiological testing followed at ……with the objective to carry out independent checks for ensuring correctness and completeness of the data recorded in records.

4.0 SCOPE:

This protocol shall be applicable for review of reported data and electronic Data of Microbiological section at …….

a. Media Preparation record
b. Media Consumption Record
c. Incubation process and relevant records
d. Autoclave Sterilization record
e. Pre Growth promotion test report evaluation
f. Post Growth promotion test report evaluation
g. Environmental monitoring record
h. Water Sampling & testing
i. Safe Microbiological Practices
j. Media Destruction record

5.0 BACKGROUND INFORMATION IDENTIFYING NEED FOR REVIEW OF MICROBIOLOGICAL TESTING PROCESSES:

This retrospective review of executed Records has been identified as a part of impact assessment for deviation no. …… initiated due to deficiency observed during MHRA inspection dated ……..

This QA review process shall be performed by an independent QA person who is trained on review of executed records.

This protocol describes the methodology and check points to review the procedure, reported data and electronic data.

The discrepancies identified through this review will be evaluated for impact on the product quality as well as human safety. This protocol will also help in identifying any data integrity issues in microbiology lab.

6.0 PROCEDURE:

6.1 Document Review

By considering the subjected matter, below mentioned points to be reviewed for past three months:

6.1.1 Review of Attendance data of the person signing the Specific record.

6.1.2 Review the traceability of the entry with other associated records like media consumption and Media Destruction etc.

6.1.3 Review the traceability of the entry with respect to the conducted activity like as Water Sampling, Water Testing, and Environmental Monitoring etc.

6.1.4 Review the operation record of Autoclave.

6.1.5 Review the temperature monitoring data of Incubator, Refrigerator.

6.1.6 Review the Garments sterilization record.

6.1.7 Review the Operation and calibration data of Colony counter.

6.1.8 Review the Operation, calibration and verification data of pH meter.

6.1.9 Review the Operation, calibration and verification data of Balance.

6.1.10 Review the Operation record of RLAF used in microbiology section.

6.1.11 Review of the training records of the persons involved in particular activity.

6.1.12 Review of any electronic records of instrument of that entry if applicable

6.1.13 Review of the availability of actual resources required for that particular activity like media/ chemicals / calibration aids

6.1.14 Review the impact of the calibration status of the pH meter used for certain application i.e. Media Preparation.

6.1.15 Document the details reviewed as per Annexure-I entitled “Check list for review of testing record of Microbiology laboratory”

6.1.16 Details of impact Assessment as per refer Annexure II.

6.2 Handling of discrepancies observed during review

6.2.1 Initiate a deviation for investigation for identifying a root cause for the discrepancies observed.

6.2.2 Perform an assessment for evaluating an impact of the deficiency on the quality of products.

6.2.3 During review if multiple significant discrepancies are identified related to recorded data in term of Data integrity then extend the review level on large scale.

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7.0 SUMMARY AND CONCLUSION:

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Reviewed By: _____ Date: _____
(Name & Signature)

Verified By: _____ Date: _____
(Name & Signature)

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8.0 APPROVAL:

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Quality Assurance (Name & Signature) **Date**

_____ _____

Quality Control (Name & Signature) **Date**

_____ _____

Head Quality Assurance (Name & Signature) **Date**