PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	**SOP No.:**
Title: Procedure for Handling Out of Specification Results in Microbiological Testing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Objective

To lay down a procedure for handling out of specification results in microbiology.

2.0 Scope

This Standard Operating Procedure is applicable for formulation plant

3.0 Responsibility

Executive/ Officer-Microbiology : Shall be responsible for following the procedure for handling out of specification results in microbiology.

Head-QC/Designee : Shall be responsible for the compliance of this SOP.

4.0 Abbreviations And Definitions

QC	:	Quality Control
SOP	:	Standard Operating Procedure

5.0 Procedure

5.1 Out of specification (OOS) results in the microbiological testing may be due to high total bacterial count and total fungal count or due to presence of any pathogen in the sample.

5.2 The following shall be treated as aberrant results that could be obtained when performing a microbial limit or bioburden test

5.2.1 Incorrect recovery of organisms such as duplicate plate count recoveries exceeding 25 percent of the mean.

5.2.2 Inoculated sample plate counts yield more than 0.5 log from the actual inoculum used.

5.2.3 Media do not meet growth promotion requirements.

5.2.4 Sample plates shows contamination.

5.2.5 Growth observed on selective agars although enrichment broths are clear.

5.2.6 Growth observed in enrichment broths but no growth obtained on non selective media when subculture.

5.3 Carry out the investigation as described in flow chart of Annexure - 1.

5.4 Laboratory investigation shall be done following the checklist as per Annexure-2.

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5.5 Retest on the resample shall be carried out, if any assignable cause is found. Investigation shall be extended to manufacturing in case of non-assignable cause.

5.6 Batch shall be rejected if assignable cause is observed during investigation at manufacturing stage.

5.7 Retest on the resample shall be carried out in case of non-assignable cause.

5.8 The sample shall be released complying with microbiological testing if repeat sample in duplicate comply with the specification.

5.9 If evidence of out of specification is observed in the retest the product fails to meet the requirements it shall be rejected and in case batch is rejected, investigation shall be extended to previous and subsequent batches to find out the root cause and to prevent reoccurrence.

5.10 This shall include the data review of all the batches manufactured on the date of manufacturing of rejected batch and to the batches manufactured on previous day and next day using.

5.11 Investigation shall be closed within one month.

6.0 Forms and Records

6.1 Flow chart for out of specification- microbiological tests : Annexure-I

6.2 Sample Checklist for Laboratory investigation : Annexure-II

7.0 Distribution

7.1 Master Copy : Documentation Cell (Quality Assurance)

7.2 Controlled Copies : Quality Control, Quality Assurance

8.0 History

Date	Revision Number	Reason for Revision
	00	New SOP

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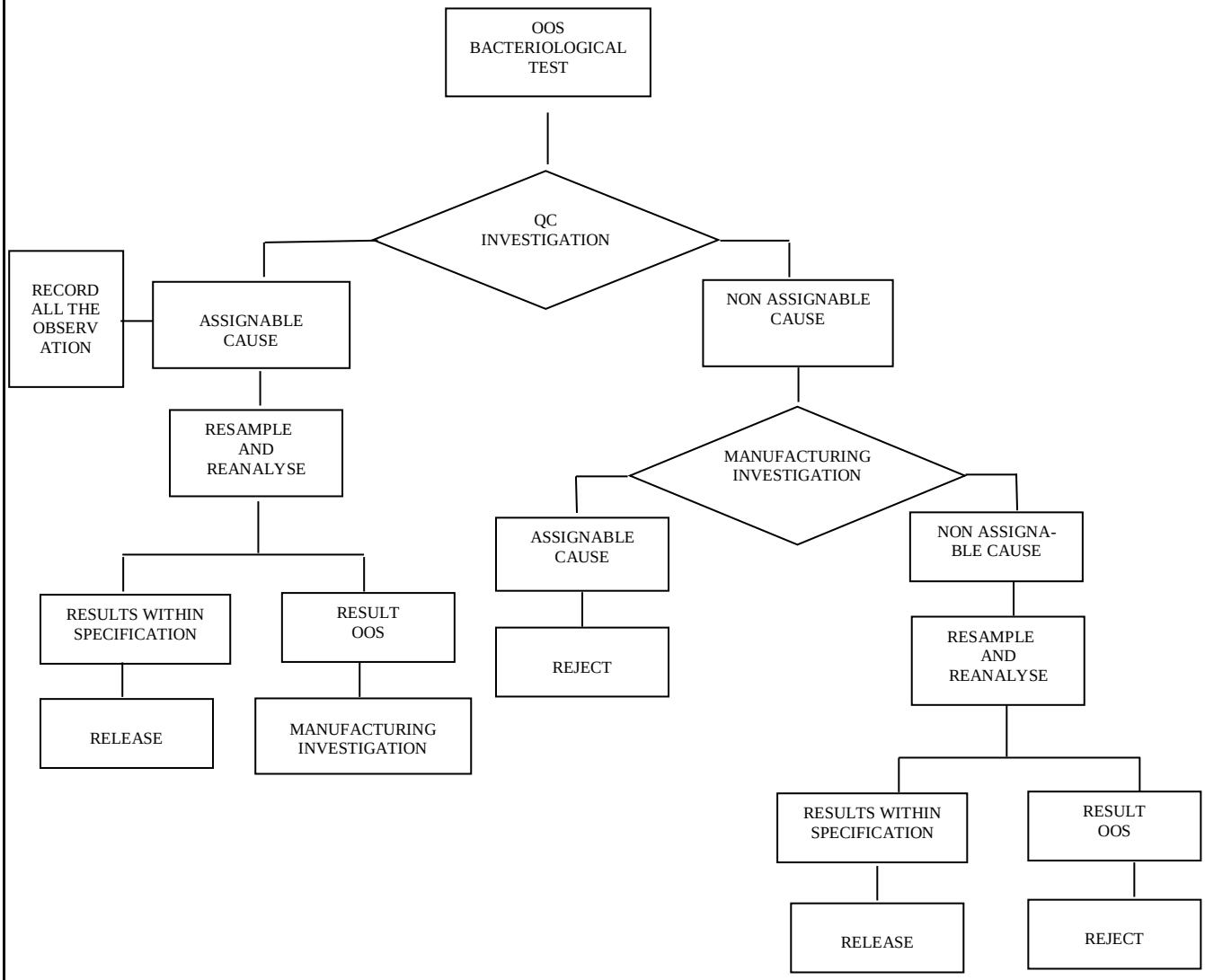
ANNEXURE I

FLOW CHART FOR OUT OF SPECIFICATION - MICROIOLOGICAL TEST



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ANNEXURE II

SAMPLE CHECKLIST FOR LABORATORY INVESTIGATION

1. Analyst/Technician training status. (OK / Not OK)
2. Compliance with test procedures. (OK / Not OK)
3. Calculation error (OK / Not OK)
4. Compliance with quality assurance policies and other related SOPs. (OK / Not OK)
5. Quality control status of media, buffers, diluents and sterilized materials. (OK / Not OK)
6. Test controls (Negative and Positive). (OK / Not OK)
7. Environmental monitoring results. (OK / Not OK)
8. Stability data, product history. (OK / Not OK)
9. Identification of isolate, possible source of contamination. (OK / Not OK)
10. Equipment calibration and maintenance status. (OK / Not OK)
11. Temperature monitoring of incubators. (OK / Not OK)
12. Method validated. (OK / Not OK)
13. Correct product specification used. (OK / Not OK)
14. Evaluation of data generated. (OK / Not OK)

Conclusion:……..

Done by:
(Sign/Date)

Reviewed by:
(Sign/Date)