1.0 OBJECTIVE

To lay down a procedure for Investigation and Handling of Out of Level (OOL) results of Environmental Monitoring in manufacturing areas, warehouse and Microbiology Laboratory area.

2.0 SCOPE

This procedure is applicable for investigation and handling of Out of Level results of Viable monitoring in manufacturing areas, warehouse and Microbiology Laboratory area of Pharma Micro Hub Pvt Ltd.

3.0 RESPONSIBILITY

3.1 **Microbiology Department:**

3.1.1 Microbiologist is responsible to intimate the out of limit results to immediate supervisor.

3.1.2 Responsible to participate in investigation.

3.1.3 Head/ Designee is responsible to review the investigation report. To ensure overall compliance of the SOP and implementation of necessary corrective and preventive action.

3.2 **Quality Assurance Department:**

3.2.1 Responsible for allotting the OOL number/investigation number.

3.2.2 Participation in investigation, review and approval of investigation report.

3.3 **Engineering Department:**

3.3.1 Responsible to participate in investigation.

3.3.2 Head/ Designee is responsible to participate in investigation and review the investigation report. Responsible to verify the implementation of necessary corrective action and preventive action.

3.4 **Production Department:**

3.4.1 Responsible to participate in manufacturing investigation.

3.4.2 Head/ Designee is responsible to participate in investigation and review the investigation report. Responsible to verify the implementation of necessary corrective action and preventive action.

4.0 PROCEDURE

4.1 **Intimation of Out of Level (OOL) results:**

4.1.1 Upon identification of Out of level results, results shall be documented in relevant logbooks and same shall be communicated to immediate supervisor, head of the department or his designee.

4.1.2 Alert level OOL shall be initiated when the count exceeds the defined Alert level.

4.1.3 Action Level OOL shall be initiated when the count meets/exceeds the defined Action level.

4.1.4 OOL number shall be taken from QA within one working day.

4.1.5 Upon receipt of OOL number, OOL intimation shall be given to user department as per the OOL intimation form.

4.2 Investigation shall be carried out in two phases as mentioned below.

- Phase-I (Laboratory Investigation)
- Phase-II (Manufacturing Investigation)

4.3 **Phase-I (Laboratory Investigation):**

4.3.1 Laboratory investigation shall be carried out to find out the root cause for the observed viable monitoring excursions.

4.3.2 Follow the procedure mentioned in the SOP for laboratory investigation.

4.3.3 As part of investigation, the below mentioned points shall be considered (But not limited to). Based on the investigation, other laboratory activities can also be considered for root cause evaluation.

- Material transfer procedure.
- Verification of plates for any contamination.
- Method followed for sampling & testing (Swab analysis).
- Materials used for sampling/testing (consumables & media)
- Verification of equipment/instrument's status used for sampling/testing.
- Interaction with the personnel involved.
- Identification of obtained colonies.
- Environmental conditions of area.
- Enumeration procedure.
- Personnel training and their qualification.
- Previous history of sampling points (Last three months).
- Subsequent monitoring results.

4.3.4 Affected area shall be monitored for three working days as applicable.

4.3.5 Investigation shall be compiled in the investigation report.

4.3.6 If the root cause is identified at laboratory level, appropriate CAPA shall be proposed as applicable.

4.4 **Phase-II (Manufacturing investigation):**

4.4.1 Manufacturing investigation shall be initiated by the user department parallel to the laboratory investigation.

4.4.2 The below mentioned points shall be considered for investigation (But not limited to).

- Training of personnel involved in activities.
- Verification of Equipment/instruments status which are relevant.
- Verification of available procedures inline to the activities.
- Area disinfection procedure.
- Material movement to aseptic areas.
- Review of environmental conditions of the area.
- Previous history.
- Aseptic practices and aseptic area entry procedure.

4.4.3 Follow the procedure mentioned in the SOP for manufacturing investigation.

4.4.4 Based on the manufacturing investigation conclusion, a CAPA shall be proposed as applicable.

4.4.5 Investigation shall be compiled in the investigation report.

4.5 **OOL Notification:**

4.5.1 Upon observing the viable excursions, document the results in respective formats, inform to head Microbiology/his designee, QA and user department through OOL intimation form.

4.5.2 OOL number shall be assigned by QA and entry shall be done in OOL Investigation numbering log .

4.5.3 OOL number shall consists of 13 characters.

4.5.4 The first two characters stands for Environmental Monitoring – EM.

4.5.5 The 3rd character is slash /.

4.5.6 The 4th to 6th characters stands for Out Of Level- OOL.

4.5.7 The 7th character is slash /.

4.5.8 The 8th and 9th characters represents the last two digits of current year.

4.5.9 10th character is slash /.

4.5.10 11th to 13th characters represent the serial number.

Eg: The first OOL generated in 2026 shall be assigned with EM/OOL/26/001 number.

4.5.11 OOL number shall be assigned by QA and log book shall be maintained by QA.

4.5.12 If multiple excursions are observed in a single day, OOL numbering shall be logged based on area wise. For easy handling of OOL's, categorization of areas is tabulated below.

Department	Categorization of area
Production	i. Aseptic area, ii. Other than Aseptic area
Warehouse	Entire warehouse shall be considered as single area
Microbiology	i. Sterility testing area, ii. Other laboratory testing area

4.5.13 OOL's shall be closed within 30 calendar days from the date of OOL results.

4.6 **Handling of Investigations:**

4.6.1 In case of Alert or Action level excursions, representative of the affected/impacted department shall request QA representative for investigation number.

4.6.2 In case of Alert or Action level excursions, OOL number shall be generated, laboratory investigation shall be carried out.

4.6.2.1 Manufacturing investigation shall be carried out by following the procedure mentioned in the SOP.

4.6.2.2 **Alert Level:** An established microbial or airborne particle level giving early warning of potential drift from normal operating conditions and triggers appropriate scrutiny and follow-up to address the potential problem. Alert levels are always lower than action levels.

4.6.2.3 **Action Level:** An established microbial or air borne particle level that when exceeded, should trigger appropriate investigation and corrective action based on the investigation.

5.0 ABBREVIATIONS

5.1 CAPA : Corrective Action and Preventive Action

6.0 FORMATS

6.1 Annexure -1 Environmental monitoring out of level results notification form

6.2 Annexure -2 Environmental monitoring out of level results log

6.3 Annexure -3 Investigation report

7.0 REFERENCES

7.1 Nil

8.0 CHANGE HISTORY

8.1 New SOP

END OF DOCUMENT

ANNEXURE-1

ENVIRONMENTAL MONITORING OUT OF LEVEL RESULTS NOTIFICATION FORM

EM OOL No.		**Date of initiation**	
Out of Limit Result Details			
Analysis name			
Location			
Observed counts	Sampling Location/ Site description	CFU	
Limit	Alert Level	Action Level	
Activity Details			
Date & Shift of Monitoring			
Monitored By Sign & Date:			
Product			
Batch No.			
Stage:			

Reported by: **Checked by:**

Sign & Date: **Sign & Date:**

Reviewed By **Head Microbiology/His Designee**	Comments: Name: Sign and Date
Received By **User Department Head/ His Designee**	Comments: Name: Sign and Date
Head QA/ His Designee (Reviewed by)	Comments: Name: Sign and Date

ANNEXURE-2

ENVIRONMENTAL MONITORING OUT OF LEVEL RESULTS LOG

Date	EM OOL No.	Type of monitoring	Area	Location / Room	Sample site description	Area Classification	Counts observed	Alert / Action	Investigation number	Date of OOL Closure	Remarks

Closed by: **Verified by:**

Sign & Date: **Sign & Date:**

ANNEXURE -3
INVESTIGATION REPORT

Description:			
Investigation Process:			
Background:			
Root Cause Analysis:			
Impact& Risk Analysis:			
Summary & Conclusion:			
Corrective Actions:			
Preventive Actions:			
Reviewed By		Approved By	