PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Handling of Microbial Excursion in Water and Environment	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1. **Purpose:** To lay down the procedure for carrying out investigation and to plan corrective action when the microbial monitoring results of environment, personnel and surface exceeds the alert/ action limits and microbiological results in water samples when exceeding the specified alert and action limits.

2. **Scope:** This Standard Operating Procedure is applicable at microbiology section of Quality Control department of …….

3. **References & Annexures:**

   3.1 **References:**

   3.1.1 USP 37 Chapter No. 61, 62, 797 and 1116

   3.1.2 Guidline for US EPA

   3.2 **Annexures:**

   3.2.1 Annexure- 1 : Flow chart for Microbiological Monitoring Excursion..

   3.2.2 Annexure- 2 : Flow chart for investigation of Environmental Monitoring excursion.

   3.2.3 Annexure- 3 : Flow chart of investigation for water Excursion (TVAC)

   3.2.4 Annexure- 4 : Flow chart of investigation for water excursion (TOC)

   3.2.5 Annexure- 5 : Result of excursion in water/Environment monitoring results.

   3.2.6 Annexure- 6 : Notification for Excursions.

   3.2.7 Annexure- 7 : Identification of microorganism

   3.2.8 Annexure- 8 : Investigation of Microbial Excursion in water and environment.

   3.2.9 Annexure- 9 : Investigation of Microbial Excursion in Water (Potable/Purified)

   3.2.10 Annexure- 10 : Investigation of Microbial Excursion in Environment.

   3.2.11 Annexure- 11 : Extension form for investigation of microbial excursion in water and environment.

4. **Responsibilities:**

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4.1 **Officer / Executive - Microbiology**

4.1.1 To inform the excursion to immediate supervisor.

4.1.2 To initiate the notification and investigation in microbiology laboratory.

4.1.3 To carry out identification of organism as required.

4.2 **Section Head-QC (Microbiology)**

4.2.1 To report excursions from alert & action limits.

4.2.2 To carry out review & investigation in microbiology laboratory.

4.2.3 To participate in investigation of excursions from alert & action limits.

4.2.4 To maintain the investigation & corrective action preventive action record (CAPA)

4.3 **Section Head-QA (Analytical Review)**

4.3.1 To Review the excursions observed of environment monitoring results and water testing results.

4.3.2 To review the phase one investigation (microbiology Lab Investigation)

4.4 **Head- Quality Control (Head-QC)**

4.4.1 Responsible for assessing the data to ascertain if the results could be attributed to laboratory error or whether the result indicates the problems in the manufacturing area.

4.4.2 Responsible for review of investigation of laboratory investigation.

4.4.3 Responsible to follow the approved protocol wherever applicable, incase of QC related action points.

4.5 **Executive/Officer-QA**

4.5.1 Responsible for issuance and generation Notification number.

4.5.2 Responsible for investigation of production process.

4.5.3 To prepare the protocol for additional investigation.

4.6 **Head Quality Assurance (Head-QA) and Head Production/Designee.**

4.6.1 Responsible for second phase investigation.

4.6.2 To carry out impact assessment, plan and execute the corrective action in the respective area.

4.6.3 To carry out the investigation of excursions from action levels in their repective area.

4.6.4 To arrange for additional sampling, as and when required for investigation.

4.7 **Site Head- Quality**

4.7.1 Responsible to ensure adequate investigation covering in the strategy development for inter and inter departmental investigations and approval of the investigation report.

4.7.2 Responsible for implementation of appropriate CAPA.

4.7.3 Responsible for approval of investigation protocol/Report.

4.8 **Regulatory Affairs, Quality Head and Plant Head:**

4.8.1 To review and approve new or revised SOPs.

5. Distribution:

5.1 QC

5.2 QA

5.3 Production

5.4 Engineering

6. Abbreviations and Definition of Terms:

6.1 **Abbreviations:**

6.1.1 AHU : Air Handling Unit

6.1.2 BMR : Batch Manufacturing Record

6.1.3 CC : Change Control

6.1.4 CAPA : Corrective and Preventive Action

6.1.5 cfu : Colony Forming Unit

6.1.6 HVAC : Heating Ventilation and Air Conditioning.

6.1.7 GPT : Growth Promotion Test.

6.1.8 NA : Not Applicable

6.1.9 No. : Number

6.1.10 OOS : Out of Specification

6.1.11 QA : Quality Assurance

6.1.12 QC : Quality Control

6.1.13 RH : Related Humidity

6.1.14 SOP : Standard Operating Procedure

6.1.15 TVAC : Total Viable Aerobic Count

6.1.16 TMC : Total Microbial Count

6.1.17 TFC : Total Fungal Count

6.1.18 Temp. : Temprature

6.1.19 UAF : Uncontrolled air flow

6.1.20 ΔP : Diffrencial Presure

6.2 **Definition of Terms:**

6.2.1 **Standard Operating Procedure (SOP):** A written authorized procedure, which gives instructions for performing operations.

6.2.2 **Microbiological Identification:** Biochemical characterization of isolated colonies to determine the isolate genus and where feasible and appropriate the species.

6.2.3 **CAPA:** Corrective and Preventive action, a systematic approach that includes actions needed to correct (correction), prevent recurrence (“corrective action”), and eliminate the cause of potential non conforming product and other quality problems (preventive action).

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

6.2.5 **Action Limit:** An established microbial or airborne particle limit that, when exceeded, should trigger appropriate investigation and corrective preventive action based on the investigation.

6.2.6 **Immediate action:** A response taken to an excursion.

6.2.7 **Corrective Action:** Action to eliminate the cause of a detected nonconformity or other undesirable situation.

6.2.8 **Preventive Action:** Action to eliminate the cause of a potential nonconformity or other undesirable situation.

6.2.9 **Critical Area:** An area designed to maintain sterility of sterile materilas. Sterilized product, containers, closures and equipment may be exposed in critical areas.

6.2.10 **Colony Forming Unit (cfu):** A microbiological term that describes the formation of a single macroscopic colony after the introduction of one or more microorganism to microbiological growth media. One colony forming unit is expressed as 1 cfu.

7. Procedure:

7.1 Flow charts for the following process are presented as Annexure

Common flow charts:

Annexure-1 For Microbiological Monitoring excursion (Will be used for both the cases)

For Environment Monitoring:

Annexure-2 For Environment Monitoring Excursions.

For Water Sample:

Annexure-3 for water excursion (TVAC)

Annexure-4 For investigation water excursion (TOC) result.

7.2 For details refer the relevant steps in the procedure. Action to be taken in case of excursion are not limited to the steps given in the procedure after approval of protocol from Site Head Quality. Action other than in the procedure may be taken in specific case based on investigation. Any discussion as a part of that review data and make recommendations should be documented and attached with the investigation report.

7.3 Notification Criteria:

7.3.1 For Environment Monitoring Excursions: following shall be the criteria for issuance of notification to the head of affected area and quality assurance through notification for excursion.

- When count of a location/ area or personnel exceeds from alert and action limit.

7.3.2 For Water Excursions: intimate for alert level excursion when the defined alert levels are exceeded (once or twice):

- If water system microbial result exceeds the alert level, constitute a warning and do not necessary require a corrective action. But additional sampling and testing shall be initated as per approved protocol to confirm the water microbiological quality of water is under control.

- Sampling shall be done from the user points, generation, storage and return loop sampling point.
- If water system microbial result exceeds action level an immediate corrective action shall be taken to bring the process back to normal operating range. Intimate for action levels or alert levels excursion when:
  - Alert Level are exceeded repeatedly (3 or more consecutive readings) or
  - Alert level are exceeded simultaneously at multiple locations (3 or more consecutive readings) or
  - A single occurrence of exceeding defined action level.

7.3.3 In case of any excursion from the microbial alert/action limits in the Settle Plate Samples, Active Air Samples, Contact Plate Samples (Wall/floor), swab samples or personnel monitoring samples and in case of any water excursion from the TOC or microbial alert/action levels as per type of water i.e is purified water/potable water, inform Quality Control Manager/Designee, the concerned department Manager/ Designee and the Quality Assurance Manager/Designee through Annexure-4 (Notification of Excursion).

7.3.4 In case of any excursion from the microbial alert/action limits in the settle plate samples, active air samples, contect plate samples (wall/floor), swab samples or personnel monitoring samples and water samples perform laboratory review of negative control. In case the negative sample is not satisfactory, initiate laboratory investigation as per investigation of microbial Excursion in water and environment (Annexure-8).

7.3.5 Head Quality Control (Head-QC)/Section Head-QC (Microbiology) shall investigation the laboratory investigation.

7.3.6 In case alert limit excursions observed three times in succession from the same location will be treated as action limit excursion. In case the laboratory review is satisfactory, inform the production Head and Head Quality Assurance of the Area.

7.3.7 Head-Quality Assurance (Head-QA) shall inform to the investigation team in consultation with microbiologist and carry out the investigation and process investigation shall be done in parallel and head QA shall take appropriate corrective action after the investigation is completed based on identification of root cause.

7.3.8 Executive/Officer-QA shall enter the details of excursion in excursion log book. Result of excursion in water/Environmental Monitoring shall be documented in Annexure-5 and Notification Number is also generated by Quality Assurance.

7.3.9 Assign the Notification Number and filling of Annexure as follows is detailed in following section.

7.3.10 **For Notification No.: Notification No. shall be such as XX/TOE/YY/nnn**

Where:

XX: Denotes Facility Code

TOE: Denotes type of Excursion (EME for Environment Monitroring Excursion and WME indicating Water Excursion)

YY: Denotes year, i.e. 21 for 2021.

nnn: Denote to seriol no. of allotted notification.

7.3.11 **Filling of Annexure:**

- After observation of excursion Officer/Executive- Microbiology shall fill the Annexure-6 as below mentioned
  - Notification No.
  - Date of observation
  - Type of Excursion
  - Date of water sampling/monitoring
  - Type of analysis
  - Sampled/Monitoring done on
  - Sample analysed by/on
  - Result observed by/on
  - Write the details such as S.No. area sampling point, Lot No./AR No. observations, alert limit, action limit, specification limit Name of the person, location time and remarks of Excursion in water sample/Environment monitoring Coolum and personnel monitoring column.
- After notification received from microbiology department Excutive/Officer-QA shall generate the Notification No. (Annexure-5) as below mentioned
  - Date of Notification
  - Excursion No.
  - Name of Facility

- Type of sample (Water/EMP)
- Sampling Point
- A.R. No./Lot No.
- Limits
- Result observed
- Investigation completion date
- CAPA recommended
- Initiated by sign/date
- Reviewed by sign/date
- Remark

- After Identification of micro organism officer/Executive-Microbiology shall fill the Annexure-7 as below mentioned.
  - Notification No.
  - Production facility/Area
  - Method of identification
  - Name of organism identified
  - Probable source identified
- Officer/Executive-Microbiology shall fill the annexure 8, 9, 10 and 11as below mentioned
  - Name of Facility
  - Type of water/sampling
  - Sampling point/location
  - Lot no./ AR. No.
  - Date of sampling
  - Date of testing
  - Result observed
  - Alert limit and action limit
  - Area classification in case of EMP

- Count observed by (Name)
- Sample by (Name)
- (√) Tick the appropriate colum where ever required
- Fill the respective colum

- For Annexure 11
  - Notification No.
  - Date of intimation
  - Due date
  - New completion date
  - Reason for extension

7.3.12 The product manufactured on the day when action limit exceeds shall be kept under hold till the completion of investigation. Appropriate decision regarding the release/rejection shall be taken by Site Head Quality/Head- Quality Assurance (Head-QA).

7.4 Identification of the microorganisms and its source.

7.4.1 Initiate identification of the microorganism upto species and genus level in case of any kind of alert or action limit excursion. Identify the possible source of the microorganism so as to locate its point of entry in the area. Posible source of the microorganism can be identify by reviewing the preveiosly isolated microorganism from different source and reviewing litrature for occurance of microorganism. Convey the information to the head of the effected area through identification of microorganism Annexure-7.

7.5 Initiate investigation as per Annexure-8 in case of three times alert excursion in succession from the same location/action limits in the settle plate samples, active air samples, contact plate samples (wall/floor/surface), swab samples or personnel monitoring samples.

7.6 Investigation of microbiology laboratory (Phase-I):

7.6.1 If the excursion is from an action level, initiate the investigation through investigation of microbial excursion in water and environment Annexure-8 (As per the type of water and type of Environment monitoring Excursion).

7.6.2 Investigate laboratory investigation, if the excursion is from microbial action level; identify the microorganisms up to species level. If cause of excursion is identified at laboratory level, carry out corrective action and re-analyze (if required), Quality Assurance shall provide additional water samples if required.

7.6.3 Analysts shall investigate for potential laboratory errors which can occur while analysis.

7.6.4 Identify the person responsible for this error and the person shall be thoroughly investigated for the failure cause and based on investigation to identify the root cause.

7.6.5 Check if samples were incorrectly stored at inappropriate temprature or containers are not properly closed or possibly not sampled in the correct designated sampling container.

7.6.6 Investigation in the microbiology laboratory shall a review of relevant records as per the Form Annexure-8. Record observation in the given space in 'Observation' coloumn. Wherever the observations are not complying, give details.

7.6.7 Check for the sampling error, ensure the sampling is done as SOP correctly.
If found that the person made shall be imparted to the responsible person and necessary evaluation is taken.

7.6.8 If laboratory error found or any mechanical failure is identified inform to Head-Quality Assurances (Head-QA) to Document the corrective action taken and the results of re-analysis (if required). If the results are complying (within the appropriate levels), conclude the investigation with the probable root cause.

7.6.9 If cause of excursion is not identified at the laboratory level, than forward the investigation report to Quality Assurance for investigation in the production or concerned area.

7.7 Investigate in manufacutring facility (Phase-II):

7.7.1 On receipt of the intimation form from microbiology laboratory, investigate the cause of excursion as per investigation of Microbial Excursion in Water as per Annexure-9 and Investigation of Microbial Excursion in Environment as per annexure-10. Production head and QA Head shall initiate the investigation for cause of failure and which will include review the records for cleaning and sanitization, changing of filters/ regenration records, disinfectant qualification record, area cleaning sanitization record, personnel qualification record, Area Qualification reports, HVAC qualification, storage and distribution, pretreatment and purification system and document the production parameters and other checks on the generation and distribution system. Identify the root cause or most probable cause. Plan appropriate corrective action such as flushing of the storage tank and the distribution loop, sanitization of the storage tank and distribution loop, quarantining the product, Area cleaning and fumigation etc.

7.7.2 After implementation of corrective action, collect samples (if required) from the particular usage point, return and supply of the purified water/Potable water storage and distribution system. Send it for analysis.

7.7.3 Record the details in the respective sampling log/register.

7.7.4 Based on the QA approval water usage may be stopped in the production to identify the failure and any further risk to the product.

7.7.5 If the re-sample of water taken meets the requirments of the test within the levels appropriate for the parameters. Resume the usage of water/steam. If the sample still fails, plan further corrective action which may include checks and sampling at the pre-tretment stages and the generation and purification stages.

7.7.6 After appropriate corrective action, again sample from the same user point, return and supply of the storage and distribution system. Based on the impact assessment, the sampling location can be increased.

7.7.7 If the results of retesting is complying (Within the appropriate levels), usage of water can resumed.

7.7.8 Provide the details of the investigation in chronological order. Assess the impact of water used during the period of excursion. Impact evaluation may include to keep the product under quarantine, additional or more extensive product testing. If the investigation reveals the root cause or source or probable source of contamination, plan appropriate corrective & preventive action.

7.7.9 Any discussion that review data and make recommendations should be documented.

7.8 Excursion limits for Personnel monitoring:

7.8.1 When the results from personnel monitoring and finger dabs are found to exceed alert or action limit or objectionable organisms are recoverd when identified as per SOP, identification of isolates, record the detail with appropriate operator/ personnel name in specific formate attached with environmental monitoring reports and inform to production department.

7.8.2 If a person exceeds action limit, he/she shall not be allowed to enter the critical area and shall be re-qualified and shall be only allowed to enter after successful completion of qualification program.

7.8.3 If a person exceed three times action limit within period of 6 month the person should be restricted and assign with work area away from the clean room facility.

7.8.4 Executive/Officer-Microbiology, Head QA and Head production will make complete review of the environmental trend data also information & comments regarding the trend data will attach to the relevant graphs and complete report will be duly signed with date and field to environmental trend data file.

7.8.5 Based on the location of excursion and the type of sample, following are the suggested additional investigational checks:

- Review aseptic technique of personnel.
- Evaluate mechanical equipment in area as possible source of contamination.
- Evaluate integrity of the room (e.g. peeling paint, cracks in ceiling, walls and floor)
- Investigate for possible sources of contamination.
- Review sterility/MLT data
- Re-train/re-qualify operator.

7.9 If the investigation reveals the source or probable source of contamination, identify the root cause and plan appropriate corrective & preventive action.

7.10 If cause for excursion cannot be identified and excursions are occurring repeatedly, check the integrity of filters of the HVAC system of the affected area. An aseptic process stimulation (media fill) may be required.

7.11 Production, if discontinued under impact assessment, shall be commenced once the environmental results of the aseptic processing area/personnel are eithin the alert/action limits.

7.12 Investigation report shall be closed within 30 working days of its initiation. In case the report is not closed, an interim report shall be prepared with the justification for extension and new proposed timelines. Fill extension from no. Annexure-11. If any extension required.

7.13 Impact Assessment and immediate corrective steps in affected area in case of excursion from environment monitoring:

7.13.1 If the notification for environmental monitoring results exceeding alert for three consecutive days or action limit then based on sampling location (Critical/Non-critical) further decision for stopping of production can be taken by Head-Quality Assurance (Head-QA) and appropriate corrective action shall be taken as given below.

- Extensive cleaning and sanitization with disinfectant.
- Fumigation of area if required
- Possibility of impact on product in filing areas

Re-training/Qualification of the personnel if count are exceeding in personnel monitoring.

7.13.2 Based on the limit of excursion, location, type of sample and product details, assess the impact on the products processed at the time of sampling and those under processing as per

form No. Annexure-9 phase-II investigation of microbial Excursion in water and Annexure-10 phase II investigation of microbial Excursion in Environment.

7.13.3 If any single excursion is observed in the critical area during batch operation, release of the batch shall be decide based on the outcome of the investigation.

7.13.4 In case of alert limits exceeding for personnel (gown) samples or finger dabes, the personnel shall be interviewed with training. In case of alert limits exceeding continuously 3 times or above action limits, the person shall be restricted from entering aseptic processing area till re-qualification of person as per personnel qualification procedure.

7.13.5 In the case the production is stopped as mentioned in 7.13.1, production activity shall be resumed after getting satisfactory results for 3 consecutive days of the environmental monitoring.

7.13.6 If the objectionable organism is repeatedly identified, appropriate corrective action shall be taken as given below.

- Source of contamination to be studied.
- Possibility of impact on product in filling araeas.
- Extensive mopping with disinfectants. If appropriate, disinfectants with specific activity such as sporicide can be used.
- Fumigation of area.
- Re-training & Qualification of the personnel if recovered in personnel monitoring.

7.14 Impact assessment and immediate corrective steps in case of excursion from water (Purified/Potable) testing results.

7.14.1 After receiving the initimation form for the exceeding alert/action levels, assess the impact based on following considerations.

- Type of sample and its usage.
- Parameters exceeding the defined levels (Microbial count, Total OrganicCarbon etc.)
- Level of excursion (Alert/Action levels)
- The sampling location (being used at which stage of product manufacturing)
- Any past history or same type of excursion.

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Annexure -1

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DEPARTMENT: MICROBIOLOGY

FLOW CHART FOR MICROBIOLOGICAL MONITORING EXCURSIONS

Observation and reporting

↓

Identification of Excursions (Micro Organism)

↓

Intimation to Section Head QC (Microbiology)

↓

Review & Intimation to Head-Quality Control

↓

Acceptation of Excursion & Notification to Head QA

↓

Head QA to review & Intimation to Production

↓

Decision of Continuation of Production by Head QA

↓

Further Head QA to decide on fate of Manufactured/Packed batches

↓

Intimation of Investigation through Notification

↓

Formation of Investigation team

↓

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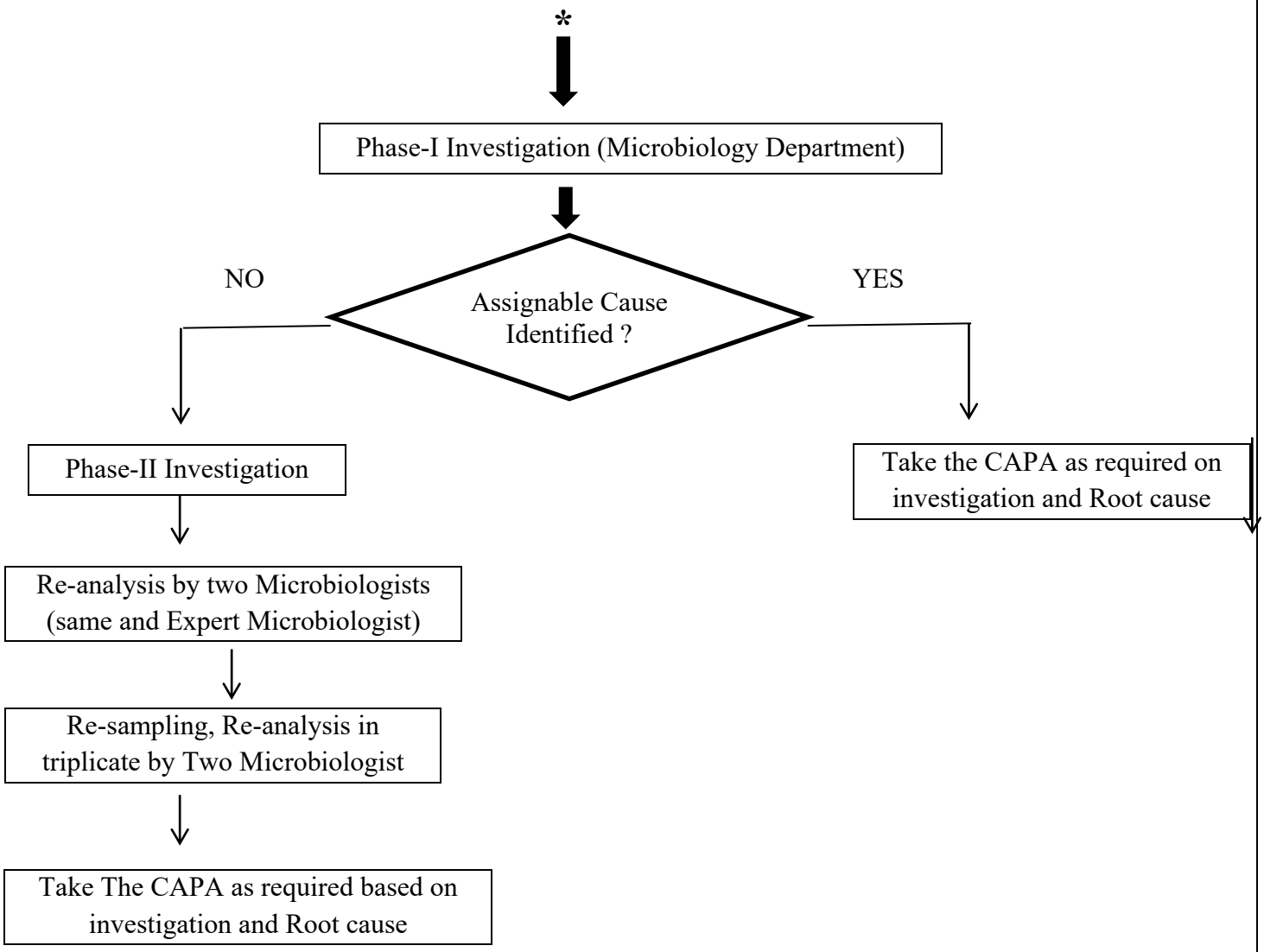

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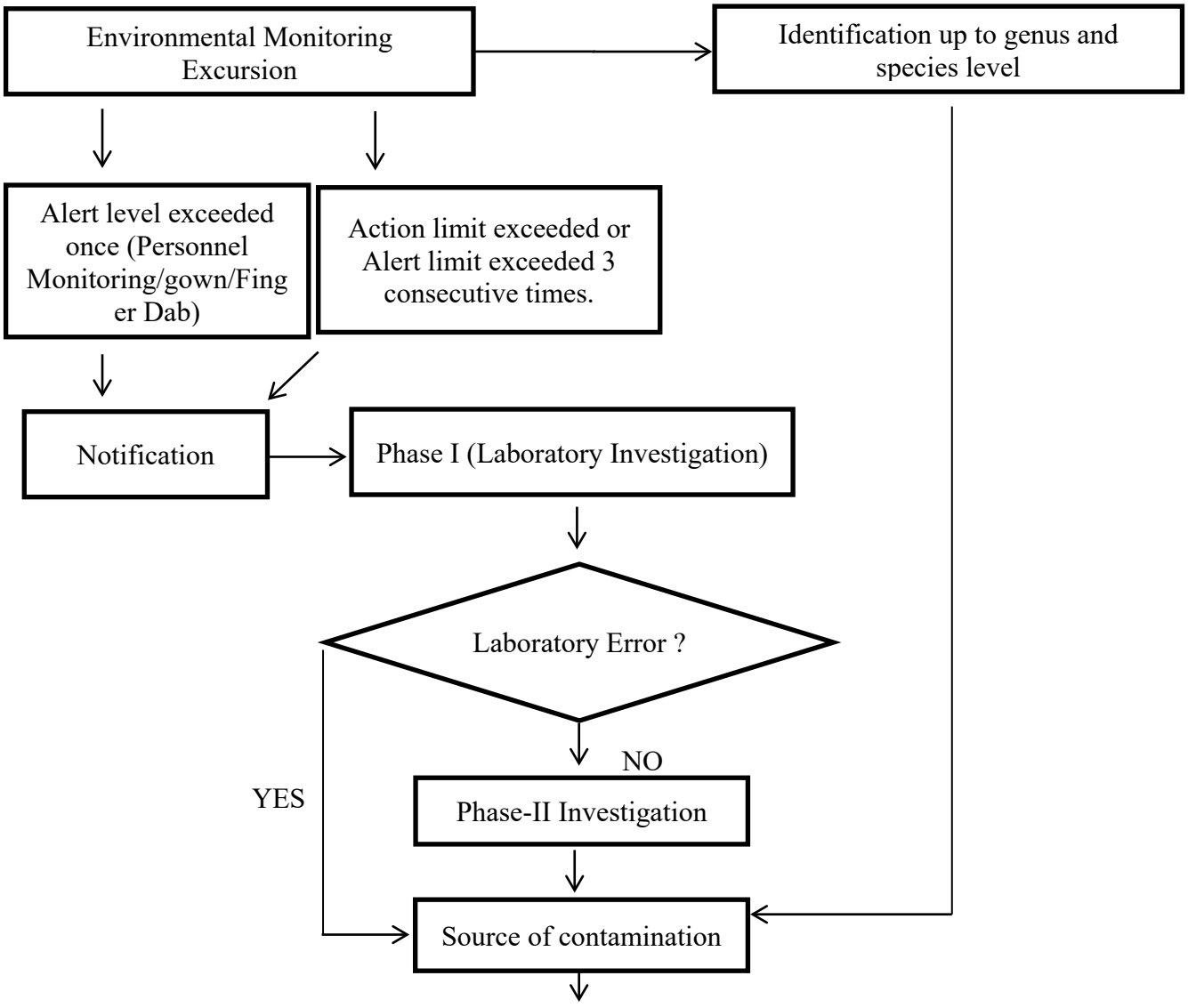
FLOW CHART FOR INVESTIGATION OF ENVIRONMENTAL MONITORING EXCURSIONS



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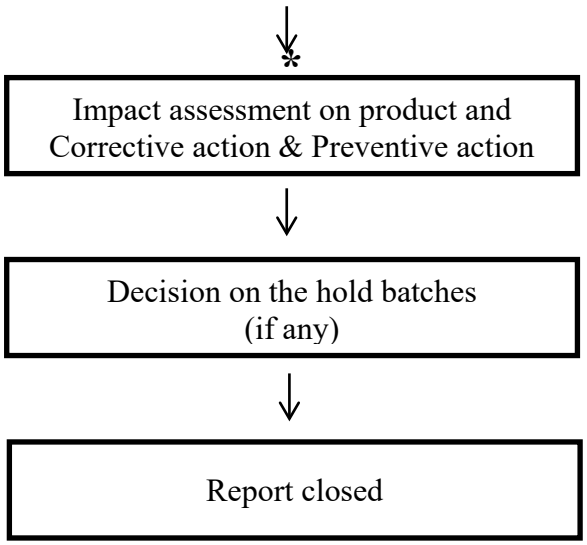

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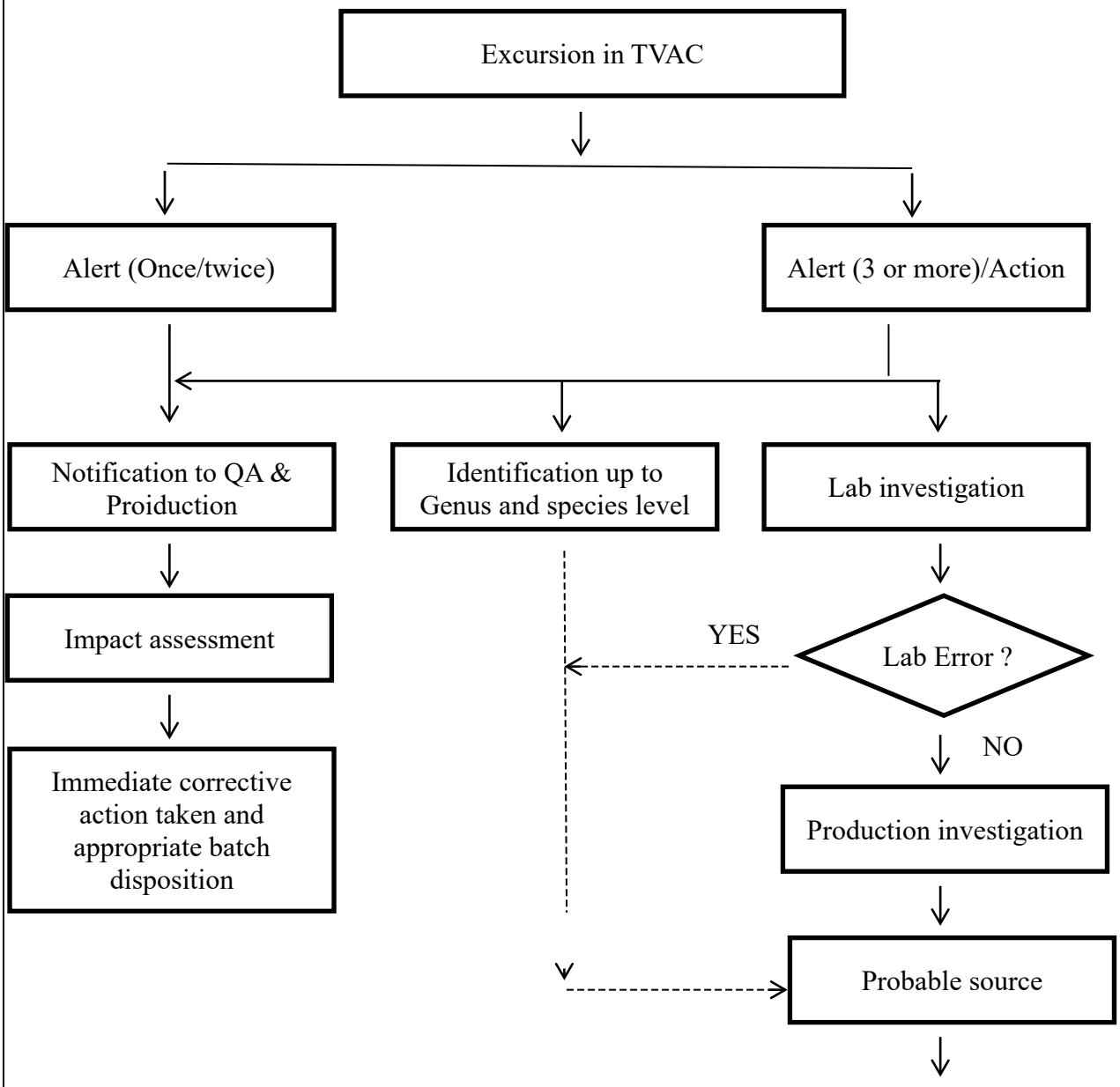
FLOW CHART OF INVESTIGATION FOR WATER EXCURSIONS (TVAC)



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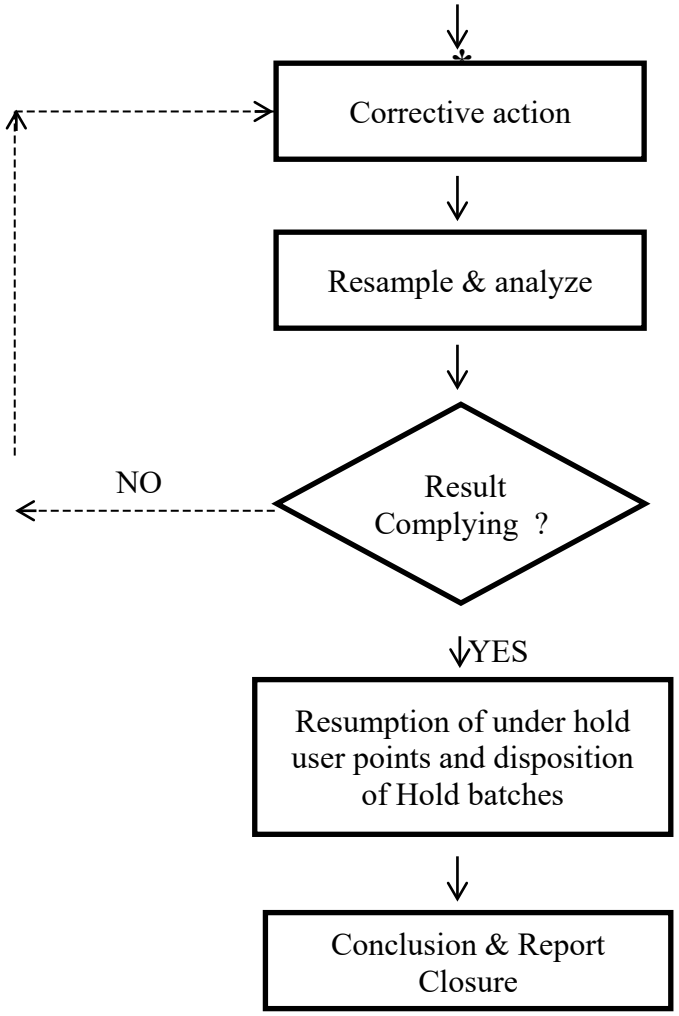

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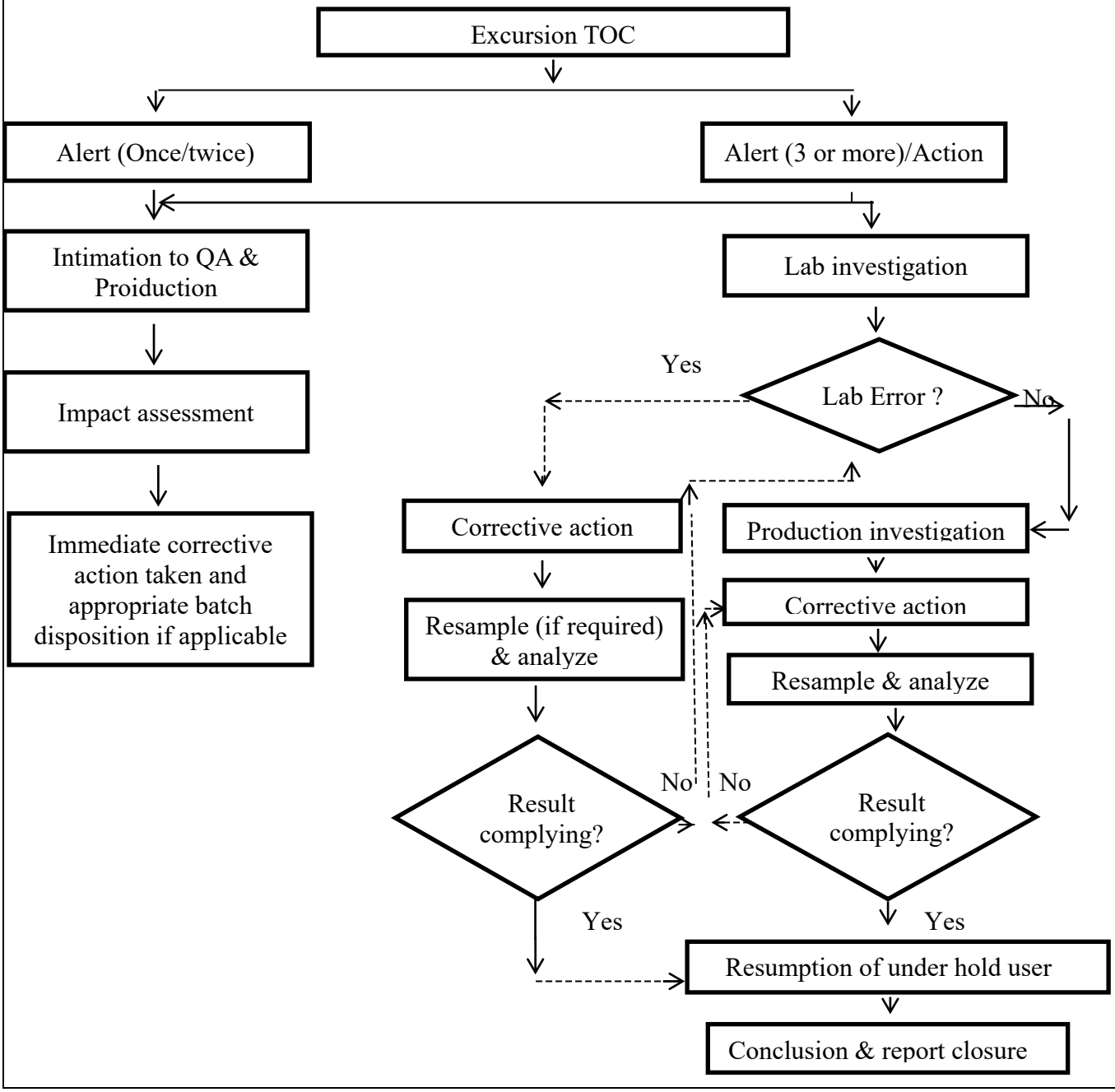
FLOW CHART OF INVESTIGATION FOR WATER EXCURSIONS (TOC)



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RESULTS OF EXCURSION IN WATER/ENVIRONMENT MONITORING RESULTS

Date of Notification	Notification No.	Type of Sample (Water/ EMP)	Sampling point/Location	AR. No./Lot. No.	Limits			Result Observed			Investigation completion data	CAPA Recommended (Yes/ No)	Initiated By Sign/Date	Reviewed by Sign/ Date	Remark
					TBC	TFC	TMC	TBC	TFC	TMC					

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NOTIFICATION FOR EXCURSION

From: QC Micro. To: Production Facility/Area: Thru: Section Head Analytical review/QA

Date of Analysis		**Type of Excursion**		**Date of water sampling/ Monitoring**		
Type of Analysis		**Sampled/ Monitoring Done on**		**Sample Analysed by/on**	**Result Observed by/on**	

Excursion details: _____

_____

(Excursion in Water Sample/Environment Monitoring)

S.No.	Area	Sampling Point	Lot No./AR. No.	Observations	Alert Limit	Action Limit	Specification Limit	Remarks

Personnel Monitoring

S.No.	Name of Person	Location	Time	Result (cfu)	Alert Level	Action Level	Observed by	Remarks

Officer/Executive (Microbiology): Sign/Date:

Section Head-QC (Microbiology): Sign/Date:

Head- Quality Control: Sign/Date:

Quality Assurance: Sign/Date:		Notification No.			
Head QA Sign./Date		Head Production Sign./Date		Head Quality Sign./Date	

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DEPARTMENT: MICROBIOLOGY

IDENTIFICATION OF MICROORGANISM

Notification no.:	
Production Facility/Area	
Method of identification	

Name of organism identified (Attach Report):

Probable source of identified organism (attach literature references, if any):

Prepared by: Officer/Executive (Microbiology) (Sign./Date)	Verified by: Section Head QA (Analytical review) (Sign./Date)	Approved by: Section Head QC (Microbiology) (Sign./Date)

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INVESTIGATION OF MICROBIAL EXCURSION IN WATER AND ENVIRONMENT (PHASE-I MICROBIOLOGY LABORATORY INVESTIGATION)

INVESTIGATION REPORT FOR EXCURSION FROM ACTION LIMIT IN WATER/EMNVIRONMENT					
Notification No.					
Name of Facility		Type of Water/ Sampling		Sampling Point/ Location	
Lot. No./ AR. No.		Date of Sampling		Date of testing	
Result observed		Alert Limit		Action Limit	
Area classification in case EMP excursion		Count observed by		Sampled by (Name)	

1. Investigation for Water excursion in TVAC/Pathogen: □ Applicable/ □ Not Applicable

Dehydrated media lot no. & expiry		Media qualification	□ Complies/ □ Does not complies/ □ Not Applicable
Autoclave cycle no. for media used for testing eg. R2A/SCDA		Autoclave cycle no. of liquid media used for testing eg. SCDM/Peptone water	
Nature of prepared media Physica appearance of solid/ liquid medium such as • Cracked containers or lids • Sterility & fertility of the media	□ Complies/ □ Does not complies/ □ Not Applicable	Pre-incubation conditions (if applicable)	□ Complies/ □ Does not complies/ □ Not Applicable

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Nature of contamination if any in pre-incubated plates		Observation of any contaminations in the plates (same media lot) used for other samples of same day and/or other days.	□ Complies/ □ Does not complies/ □ Not Applicable
Any unusual observation during preparation of media (In dehydrated, upon reconstitution & dissolution, pH, post sterilization), storage and usage	□ Complies/ □ Does not complies/ □ Not Applicable	Negative control of SCDM/R2A/SCDA/ Diluents	□ Complies/ □ Does not complies/ □ Not Applicable
Growth promotion test result of used media	□ Complies/ □ Does not complies/ □ Not Applicable	pH of Media	□ Complies/ □ Does not complies/ □ Not Applicable
0.45µ membrane negative control on Agar media.	□ Complies/ □ Does not complies/ □ Not Applicable	Was there any crack, improper closures observed in the sampling containers?	□ Complies/ □ Does not complies/ □ Not Applicable
Environmental monitoring of LAF (Used for analyzing the samples under investigation) Settle plate results and Active air sampling results (3 days)	□ Complies/ □ Does not complies/ □ Not Applicable	Environmental monitoring of associated and background environment (Used for analyzing the samples under investigation) Settle plate results and Active air sampling results (3 days)	□ Complies/ □ Does not complies/ □ Not Applicable

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Trend analysis of environmen monitoring of the LAF and background area including the personal monitoring	□ Complies/ □ Does not complies/ □ Not Applicable	Results of TVAC/Pathogen 3 dyas earlier	□ Complies/ □ Does not complies/ □ Not Applicable
Power failure during testing	□ Yes/ □ No	Preparation and sterilization of accessory	□ Complies/ □ Does not complies/ □ Not Applicable
Analyst training (Microbiologist)	□ Complies/ □ Does not complies/ □ Not Applicable	Verification of sterilization Load	□ Complies/ □ Does not complies/ □ Not Applicable
Analyst Qualification	□ Complies/ □ Does not complies/ □ Not Applicable	Review of periodic cleaning of Pre-filter	□ Complies/ □ Does not complies/ □ Not Applicable
Any Previous history of the sample under investigation, analyst involved in testing	□ Complies/ □ Does not complies/ □ Not Applicable	Ensure the sampling is done as per SOP.	□ Complies/ □ Does not complies/ □ Not Applicable
Sampling Bottles sterilization	□ Complies/ □ Does not complies/ □ Not Applicable	Qualification/Validation of sterilization process	□ Complies/ □ Does not complies/ □ Not Applicable
Qualification / Validation of LAF	□ Complies/ □ Does not complies/ □ Not Applicable	Standard operating procedure and standard testing procedure adopted for the testing of samples under investigation.	□ Complies/ □ Does not complies/ □ Not Applicable

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Any unusual observation during sampling (To be verified by means of an interview with the analyst. Who has done the sampling)	□ Complies/ □ Does not complies/ □ Not Applicable	Other observation (if any)	□ Complies/ □ Does not complies/ □ Not Applicable
Interview of person for potential cause (Attached report if required)	□ Complies/ □ Does not complies/ □ Not Applicable		
Investigation Evaluation summary:			
2. Investion for Environment Monitoring □ Applicable/ □ Not Applicable			
Steam Sterilizer (Instrumrnt ID.)		Steam Sterilizer Validation done on.	
Results of steam Sterilizer Validation	□ Complies/ □ Does not complies	Steam Sterilizer Validation due on.	
Deviation if any. (To be compare with previous case)	□ Yes/ □ No	Media Name & Lot No. used for environment monitoring.	
Validity period of sterilized media.		Date of media sterilization	
Sterilization cycle no.		Media plate prepared by (Name)	
Status of Negative control	□ Complies/ □ Does not complies/ □ Not Applicable	Review the sterilization parameters	□ Complies/ □ Does not complies/ □ Not Applicable

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Review the result of media GPT	□ Complies/ □ Does not complies/ □ Not Applicable	Date of petriplates sterilization	
Lot. No./used before of pre-sterilization Petriplates.		Review of training records of concern/microbiologist	□ Complies/ □ Does not complies/ □ Not Applicable
Petri plates sterilization cycle no.		Preincubation of media plates completed(Date)	
Preincubation of media plates started (Date)		Preincubation of plate status (Any contamination found)	□ Complies/ □ Does not complies/ □ Not Applicable
Review the microbial monitoring result of media preparation room is within the alert level on the day of media prepared.	□ Complies/ □ Does not complies/ □ Not Applicable	Name & concentration of sanitizing/Cleaning agent used.	
Area cleaning & sanitization done as per SOP.	□ Complies/ □ Does not complies/ □ Not Applicable	Review the area qualification record found satisfactory/not satisfactory	□ Complies/ □ Does not complies/ □ Not Applicable
Review the Environmental condition plate preparation room (Temp, RH & ΔP).	□ Complies/ □ Does not complies/ □ Not Applicable	Preparation and Validity dates for disinfectants used.	□ Complies/ □ Does not complies/ □ Not Applicable
Review the vible microbial monitoring trends of microbiology laboratory (Two Months).	□ Complies/ □ Does not complies/ □ Not Applicable	Review of the Non viable count if required	□ Complies/ □ Does not complies/ □ Not Applicable

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Verify the entry exit procedure for microbiology area weather the entry made correctly	□ Complies/ □ Does not complies/ □ Not Applicable	Review the procedure adopted to perform the test was correct or not	□ Complies/ □ Does not complies/ □ Not Applicable
Review the isolate and their source and there occurance with other type of tests such as bio-burden, microbial limit test, sterility test and water analysis.	□ Complies/ □ Does not complies/ □ Not Applicable	Check the any similar observation occurred previously, their investigation and corrective action taken.	□ Yes/ □ No
Review the cleaning & sanitization status of transportation container	□ Complies/ □ Does not complies/ □ Not Applicable	Sterilization date of peptone water bottle.	
Container sterilization cycle no./Sanitization done.		Sterilization date of Air Sampler sieve	
Air Sampler sieve sterilization cycle no.		Sterilization cycle parameter (container/Air sampler sieve)	□ Complies/ □ Does not complies/ □ Not Applicable
Microbiology deparment HVAC validation due on.		Results of HVAC Validation	□ Complies/ □ Does not complies/ □ Not Applicable
Deviation in (HVAC Validation) if any	□ Yes/ □ No	To check microbiologist qualifivcation record	□ Complies/ □ Does not complies/ □ Not Applicable

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To check environmental reports other than the failure report for for previous excursion if any	□ Complies/ □ Does not complies/ □ Not Applicable	Check the starilization status of the materials used for test was correct eg. Media, Filter paper, Water, Swabs, Saline etc.	□ Complies/ □ Does not complies/ □ Not Applicable
Check the history of the data	□ Complies/ □ Does not complies/ □ Not Applicable	Review of isolated organism obtained with orevious history	
Review reports of the laminar flow in micro lab and the other testing reports of microbiology lab.	□ Complies/ □ Does not complies/ □ Not Applicable	Review for occurrebce of any particular intervention in microbiology lab.	□ Complies/ □ Does not complies/ □ Not Applicable
Investigate whether performance of any equipment or training of personnel or use of apparatus have not affected the results of the tests performed at that time.	□ Complies/ □ Does not complies/ □ Not Applicable	Any other cause/points for excursion	□ Complies/ □ Does not complies/ □ Not Applicable
Corrective action and Prevantive action (Mentioned CAPA taken, in bref also mention CAPA reference No.)			

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INVESTIGATION OF MICROBIAL EXCURSION IN WATER AND ENVIRONMENT (PHASE-I MICROBIOLOGY LABORATORY INVESTIGATION)

Assignable cause Found/Not Found initiate the second phase investigation	

Investigation Evaluation Summary:

Conclusion:

Officer/Executive-Microbiology (Sign/Date)	Section Head-QA (Analytical Review) (Sign/Date)	Section Head-QC (Microbiology) (Sign/Date)
Head-Quality Control (Sign/Date)	Head-Quality Assurance (Sign/Date)	Head-Quality (Sign/Date)

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INVESTIGATION OF MICROBIAL EXCURSION IN WATER
(PHASE-II PRODUCTION AREA INVESTIGATION)

Notification No.:

1. Potable Water Treatment: □ Applicable/ □ Not Applicable

Check the chlorination/ Disinfection tretment	□ Complies/ □ Does not complies/ □ Not Applicable	Check the SMBS dosaing	□ Complies/ □ Does not complies/ □ Not Applicable
Check the Hardness of water	□ Complies/ □ Does not complies/ □ Not Applicable	Verify the Ion exchange parameters	□ Complies/ □ Does not complies/ □ Not Applicable
Check the effectiveness of filtration	□ Complies/ □ Does not complies/ □ Not Applicable	Cleaning frequency of raw water storage tank.	□ Complies/ □ Does not complies/ □ Not Applicable
Any other parameter if required (As per water treatment system)	□ Complies/ □ Does not complies/ □ Not Applicable	Any unusual observation incidence occurs.	□ Yes/ □ No
Training Record of Concern person	□ Complies/ □ Does not complies/ □ Not Applicable		

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INVESTIGATION OF MICROBIAL EXCURSION IN WATER
(PHASE-II PRODUCTION AREA INVESTIGATION)

2. Purified Water Generation, Storage and Distribution System: □ Applicable/ □ Not Applicable			
Last sanitization done on		Check the online conductivity for any abnormal trend in purified water	□ Complies/ □ Does not complies/ □ Not Applicable
Check for any leakage in purified water generation system.	□ Complies/ □ Does not complies/ □ Not Applicable	Check for calibration status of temprature, Conductivity & pressure sensors.	□ Complies/ □ Does not complies/ □ Not Applicable
Check the ternd of TVAC return loop water	□ Complies/ □ Does not complies/ □ Not Applicable	Check for the change in conductivity from the set limit for last 7 days of storage tank.	□ Complies/ □ Does not complies/ □ Not Applicable
Check for the change in conductivity from the set limit for last 7days of return loop.	□ Complies/ □ Does not complies/ □ Not Applicable	Check for the change in vilocity from the set limit for last 7days.	□ Complies/ □ Does not complies/ □ Not Applicable
Check for UV parameters as per limit.	□ Complies/ □ Does not complies/ □ Not Applicable	Check for the decrease in water level below the limit for last 7 days.	□ Complies/ □ Does not complies/ □ Not Applicable

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INVESTIGATION OF MICROBIAL EXCURSION IN WATER
(PHASE-II PRODUCTION AREA INVESTIGATION)

Check for the last vent filter integrity done on & test results	□ Complies/ □ Does not complies/ □ Not Applicable	Check for any maintenance work done/date	□ Complies/ □ Does not complies/ □ Not Applicable
Check for any leakage in distribution system	□ Complies/ □ Does not complies/ □ Not Applicable	Values of critical parameters of RO system are as per the set limit.	□ Complies/ □ Does not complies/ □ Not Applicable
Any other parameters	□ Complies/ □ Does not complies/ □ Not Applicable	Any unusual observation incidence occurs.	□ Yes/ □ No
Interview of operator for potential cause (Report attached if required)	□ Yes/ □ No	Training record of concern person	□ Complies/ □ Does not complies/ □ Not Applicable
Investigation Evaluation Summary:			

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INVESTIGATION OF MICROBIAL EXCURSION IN WATER
(PHASE-II PRODUCTION AREA INVESTIGATION)

Finding of investigation and final conclusion	
Investigation details (Provide details in chronology order. Attach all supporting documents and details of isolates identified, if applicable):	
Root cause/Probable Root cause	
Impact assessment	
Corrective action and Preventive action (Mentioned CAPA taken, in brif also mention CAPA reference No.)	
Final conclusion :	
Head- Preoduction: Sign./Date:	Head –Quality Assurance: Sign./Date:
Site Head Quality: Sign./Date :	

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INVESTIGATION OF MICROBIAL EXCURSION IN ENVIRONMENT

Notification no.		Name of Production Facility/Area	
Date of sampling		Sampling Location	
Type of Sampling		Area Classification	

PHASE-II Review & Investigation in Affected Area/Manufacturing area			
Review microbiological environment monitoring results of adjacent locations of affected area.	□ Complies/ □ Does not complies/ □ Not Applicable	Review microbiological Environment monitoring trend (Last 60 Days)	□ Complies/ □ Does not complies/ □ Not Applicable
Review of microbial personnel monitoring results	□ Complies/ □ Does not complies/ □ Not Applicable	Review microbiological Personnel monitoring trend (Last 60 Days)	□ Complies/ □ Does not complies/ □ Not Applicable
Review the temprature,RH & ΔP of area trend (Last 60 days)	□ Complies/ □ Does not complies/ □ Not Applicable	Review the ΔP of UAF trend	□ Complies/ □ Does not complies/ □ Not Applicable
Review the no. of persions worked in the aseptic processing area data and no.	□ Complies/ □ Does not complies/ □ Not Applicable	Review the qualification status of personnel entered in aseptic area.	□ Complies/ □ Does not complies/ □ Not Applicable

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INVESTIGATION OF MICROBIAL EXCURSION IN ENVIRONMENT

Review the nature of activity performed in room.	□ Complies/ □ Does not complies/ □ Not Applicable	Review the maintenance activity performed in area if any.	□ Complies/ □ Does not complies/ □ Not Applicable
Check the personnel health/hygiene	□ Complies/ □ Does not complies/ □ Not Applicable	Review the usage of sterilized garments within the hold time.	□ Complies/ □ Does not complies/ □ Not Applicable
Verify the condition of sterilized garments	□ Complies/ □ Does not complies/ □ Not Applicable	Review the load pattern of sterilization cycle.	□ Complies/ □ Does not complies/ □ Not Applicable
Name and concentraion of sanitizing agents used.		Preparation & expiry dates of disinfectants used.	
Claning & sanitization performed by		Review of training records of the personnel.	□ Complies/ □ Does not complies/ □ Not Applicable
Items passing to the aseptic processing area done as per SOP.	□ Complies/ □ Does not complies/ □ Not Applicable	Power failure if any	

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INVESTIGATION OF MICROBIAL EXCURSION IN ENVIRONMENT

Abnormal observation if any	□ Yes/ □ No	HVAC Validation done on	
HVAC Validation due on		Deviation if any results of HVAC validation	□ Complies/ □ Does not complies/ □ Not Applicable
Check entry/exit records for critical area.	□ Complies/ □ Does not complies/ □ Not Applicable	Personnel's entered the area on the day count exceeds alert/action level, whether the entry/exit procedure was followed as per SOP.	□ Complies/ □ Does not complies/ □ Not Applicable
Review the gowning Qualification of the personnel's enter in critical area.	□ Complies/ □ Does not complies/ □ Not Applicable	Check cleaning and sanitization record and usage of qualified disinfectants and their preparation as applicable.	□ Complies/ □ Does not complies/ □ Not Applicable
Check the personnel qualification record to enter in critical area.	□ Complies/ □ Does not complies/ □ Not Applicable	Check the RH temprature and diffrential pressure.	Check the RH temprature

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INVESTIGATION OF MICROBIAL EXCURSION IN ENVIRONMENT

Evaluate BMR and check the duration of the filling.	□ Complies/ □ Does not complies/ □ Not Applicable	Check AHU operation log	□ Complies/ □ Does not complies/ □ Not Applicable
Check sterilization details for equipments/garments/accessories used on that particular day	□ Complies/ □ Does not complies/ □ Not Applicable	Check water system regeneration/sanitization record i.e. when it was done foe the last.	□ Complies/ □ Does not complies/ □ Not Applicable
Verify the sanitization and disinfection record.	□ Complies/ □ Does not complies/ □ Not Applicable	Check the persionnel hygening of the personnel involved	□ Complies/ □ Does not complies/ □ Not Applicable
HVAC break down occurred during the exposure.	□ Complies/ □ Does not complies/ □ Not Applicable	Evalute filter integrity records of all filters including autoclave vent filter integrity record	□ Complies/ □ Does not complies/ □ Not Applicable
Check the validation of AHU. Autoclave, Tunnel, Filter and sanitizer effecay.	□ Complies/ □ Does not complies/ □ Not Applicable	Any other point/cause	□ Complies/ □ Does not complies/ □ Not Applicable
Interview operators (s) for potential cause:			

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INVESTIGATION OF MICROBIAL EXCURSION IN ENVIRONMENT

Investigation Evaluation Summary:	
Probable cause for excursion (Based on isolate):	
Impact assessment	
Corrective action and Preventive action (Mentioned CAPA taken, in brif also mention CAPA reference No.)	
Conclusion	

Head- Preoduction:
Sign./Date:

Head –Quality Assurance:
Sign./Date:

Site Head Quality:
Sign./Date :

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EXTENSION FROM FOR INVESTIGATION OF MICROBIAL EXCURSION IN WATER AND ENVIRONMENT

Type of Record: review and investigation in microbiology & production for Environmental Monitoring Excursion & Production for Water Monitoring Excursion

Notification No.		Date of Intimation	
Due Date		New Completion Date	

Reason for Extension:

Extension Taken By: Sign./Date	Head Quality Sign./Date	Site Quality Head Sign./Date

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8. History:

Revision No	Effective Date	Revision Details	CC No
00		New SOP	NA