



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Handling Results Beyond Alert Level / Action Level / Regulatory Specifications in Purified Water	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 Objective

To lay down a procedure for Handling Results Beyond Alert Level / Action Level / Regulatory Specifications in Purified Water.

2.0 Scope

This Standard Operating Procedure is applicable for formulation plant.

3.0 Responsibility

Executive/Officer-QC : Responsible to follow the Standard Operating Procedure for Handling Results Beyond Alert Level / Action Level / Regulatory Specifications in Purified Water.
Head - QC/Designee : Shall be responsible for compliance of SOP.

4.0 Abbreviations

SOP : Standard Operating Procedure
QC : Quality Control
QA : Quality Assurance
Engg. : Engineering
NCR : Non-Conformance Report

5.0 Procedure

5.1 If the water quality parameters exceed the alert level, allow the water consumption and follow the investigation procedure as given below:

5.1.1 Investigate the matter by reviewing the available physio-chemical data and verify the accuracy of test procedure, sampling procedure, sample handling and storage and laboratory environment monitoring, if any discrepancies are found, declare the results invalid and confirm the results by re-sampling and reanalysis.

5.1.2 If the water fails after re-sampling and analysis then inform to QA / Production / Engg. Dept. to investigate the root cause by reviewing the data available of system



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operation, calibration, performance verification, maintenance, cleaning, sanitization, regeneration and distribution to take appropriate corrective and preventive actions, if required.

5.2 If the water quality parameters exceed the action level, raise NCR and inform production department not to use the water for manufacturing and follow the investigation procedure as given in point no. 5.1.1 and 5.1.2:

5.3 Follow the criteria given below for analysis of samples which is based on Performance Qualification of Purified Water System.

Parameter	Alert Level	Action Level	Regulatory Specification
pH	6.59	6.79	-
Conductivity	0.86 $\mu\text{S}/\text{cm}$	0.94 $\mu\text{S}/\text{cm}$	1.3 $\mu\text{S}/\text{cm}$
Total Microbial Counts	23 cfu/ml	28 cfu/ml	100 cfu/ml
TOC	-	-	500 ppm

6.0 Forms and Records

6.1 Annexure-1: Flow Chart for Handling Results beyond Alert Level/Action Level/ Regulatory Specifications in Purified Water

7.0 Distribution

Master Copy : Documentation Cell (Quality Assurance)

Controlled Copies : Quality Control, Quality Assurance, Engineering and production.

8.0 History

Date	Revision Number	Reason for Revision
		New SOP



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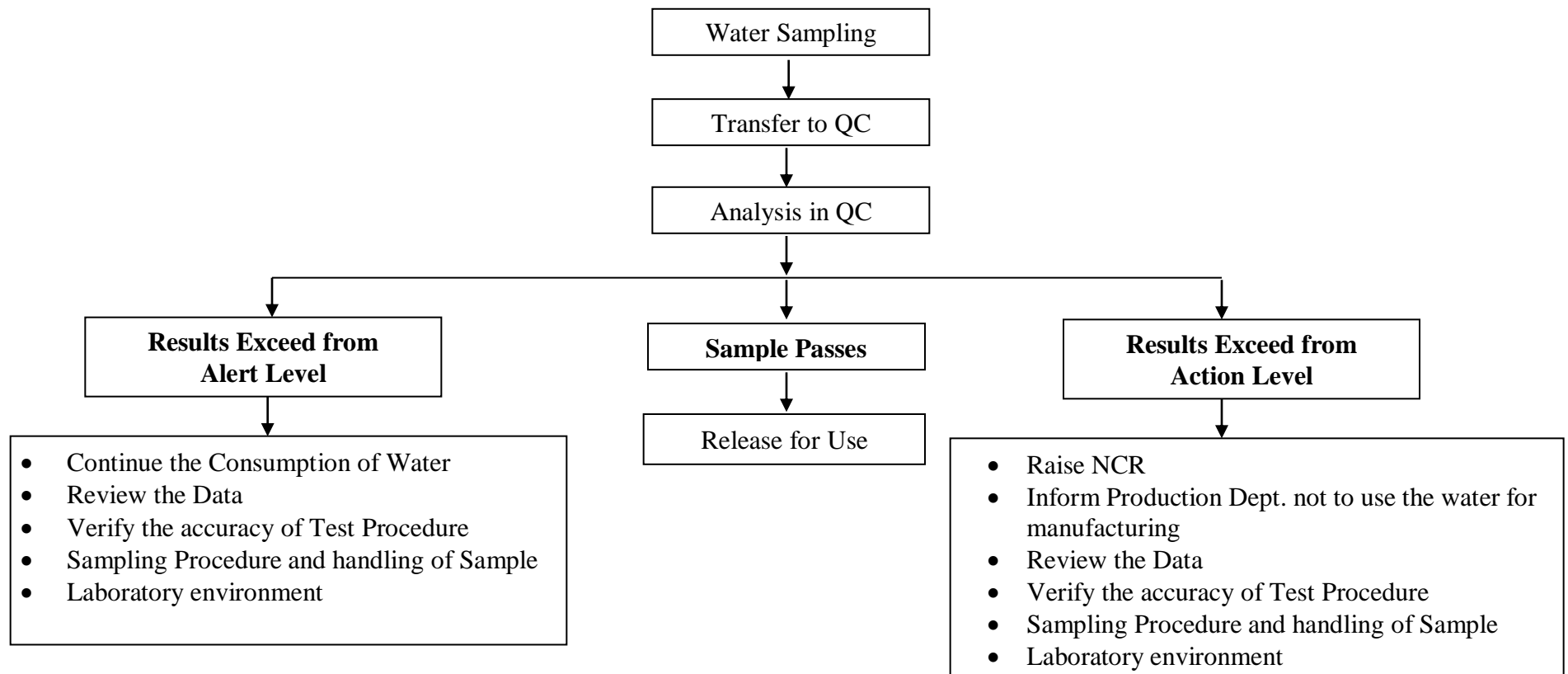
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ANNEXURE I

Flow Chart for Handling results beyond Alert Limit/Action Limit/Regulatory Specifications





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If any discrepancies found, declare the results invalid

- ↓
- Confirm Results by Re sampling and Analysis
 - Intimate to QA/Production/Engg to investigate the root cause of failure

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