QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR ENVIRONMENTAL MONITORING

Reference Document No.:	Risk Assessment No.:

PROTOCOL

FOR

RISK MANAGEMENT OF ENVIRONMENT

MONITORING

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1.0 Protocol Approval

	Prepared By	**Checked By**	**Approved By**
Signature			
Name			
Date			
Dept.	Officer (Microbiology)	Manager Q.C.	Manager Q.A.

2.0 OBJECTIVE:

The objective of this protocol is to challenge risk management in environment monitoring studies.

3.0 SCOPE:

This protocol describes the procedure for risk management in environment monitoring studies.

4.0 VALIDATION TEAM:

Officer - Microbiology

Executive - Microbiology

Manager – Quality Assurance

Note:
(a) In absence of head of the department, his designee shall be considered as Validation Core Committee member.
(b) Mention name of the Qualification Team members in report.

5.0 RESPONSIBILITY:

5.1 Quality Control (Microbiology Section):

To prepare protocol and report and execution of study.

5.2 Quality Assurance:

To approve protocol & report.

6.0 RE-VALIDATION CRITERIA:

Revalidation is performed:

a) Change in disinfectant
b) Change in AHU system
c) Any other changes which affects Environment.

7.0 REQUIREMENTS:

7.1 Medium used for validation:

1) Soyabean Casein Digest Agar(SCDA)

7.2 Glassware: Sterile pipettes; Sterile Petri plates, conical flask.

7.3 Equipments:

1) Autoclave (ID. NO.: …….)
2) Incubator (ID. NO.: ……..for incubation at 30-35 ° C temperature).
3) Incubator (ID. NO.: ……..for incubation at 20-25 ° C temperature).

8.0 PROCEDURE:

8.1.1 Media exposure plates are prepared as per SOP & check them visually.

8.1.2 Expose the plates in double no. of quantity one at the routine location and other just opposite to the routine locations

8.1.3 Plates are exposed in following areas at various places for 4 hrs.

8.1.4 Incubate the plates at 30-35°C for 3 days & 20 - 25° C for 2 days.

8.1.5 Trend of environment count checked.

8.1.6 Places where maximum counts are observed are taken for plates exposure for routine monitoring.

9.0 ABBREVIATIONS:

Q.A.	:	Quality Assurance
Q.C.	:	Quality Control
cfu / ml	:	colony forming unit

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Annexure – I

Day/date

S. No.	Routine Sampling Location	Extra Sampling Location	Results		Analyzed by	Checked by	Remarks
			Routine Sampling Location	Extra Sampling Location			

Compiled BY	Checked By	Checked By	Approved BY
Officer QA	Head –Q.C.	Head Production	Head- Q.A.
Date :	Date :	Date :	Date :