



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 1 of 19

**REPORT
FOR
TEMPERATURE MAPPING
OF
BOD INCUBATOR**

AREA: MICROBIOLOGY LAB (QA/QC BLOCK)

LOCATION: BET/MLT LAB

Document No.	
Supersedes	
Ref. Protocol No.	
Date of Final Approval	
No. of Pages	



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 2 of 19

REPORT CONTENTS

S. No.	Section Title	Page No.
1.0	Report Approval.....	3
2.0	Overview	4
	2.1 Objective.....	4
	2.2 Purpose and Scope.....	4
	2.3 Responsibility.....	4
	2.4 Qualification Team.....	4
3.0	Training Record.....	5
4.0	Pre – Qualification Requirements.....	6
5.0	System / Equipment Description	7
6.0	Temperature Mapping Procedure	7
7.0	Acceptance Criteria	8
8.0	Summary and Conclusion	8
9.0	Approval of Qualification Report	8
10.0	Observed Deviation	9
11.0	List of Exhibits/Annexures	10
12.0	Reference Documents (If Any)	10



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 3 of 19

1.0 Report Approval:

This is a specific report for Temperature Mapping of BOD Incubator (.....), which is lying in the Incubator room, Microbiology lab (QA/QC Block).

Initial Approval

This protocol has been approved by the following

Prepared By:

Name	Designation	Department	Signature	Date

Checked By:

Name	Designation	Department	Signature	Date

Final Approval:

Name	Designation	Department	Signature	Date



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 4 of 19

2.0 Overview

2.1 Objective

To establish the methodology for temperature mapping of BOD Incubator (Equipment No.:) which is kept in the BET/MLT lab in Microbiology lab (QA/QC Block).

2.2 Purpose and Scope

The purpose of this report is to establish documentary evidence that BOD Incubator (Equipment No.:) has been qualified to ensure uniformity of temperature at different locations for the incubation of the samples plates.

This report is applicable for the temperature mapping of the BOD Incubator (Equipment No.:) which is kept in the BET/MLT lab in Microbiology lab (QA/QC Block).

2.3 Responsibility

- **Protocol / Report Preparation:** Executive Microbiology
- **Protocol / Report checking :** Manager QC / Manager Maintenance/ Manager QA
- **Approval of Protocol / Report:** Head QA
- **Execution of Qualification Activity:** Executive Microbiology / Executive Engineering

2.4 Qualification Team

- Microbiologists/Executive Microbiology
- Engineering Executive / Manager
- Quality Assurance Executive / Manager



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 5 of 19

3.0 Training Record:

3.1 Purpose

The purpose of the training is to familiarize the trainees with overall strategy of temperature mapping of BOD Incubator (Equipment No.:).

3.2 Scope

This Training is applicable to the temperature mapping procedure of the BOD Incubator Equipment No. -

3.3 Topics

The following topics have been covered during training:

- Overall strategy of temperature mapping procedure.
- General precautions / guidelines to be followed during qualification.

- *Training record has been attached with the report as Annexure – 01.*



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 6 of 19

4.0 Pre – Qualification Requirements

Following instruments were required for the temperature mapping of the BOD Incubator (Equipment No.:).

S.No.	Instrument Name	Instrument Code / S.No.	Calibration Certificate No.	Calibration Due On
1.	Data logger			
2.	Temperature Sensors			
3.	Temperature Sensors			
4.	Temperature Sensors			
5.	Temperature Sensors			
6.	Temperature Sensors			
7.	Temperature Sensors			
8.	Temperature Sensors			
9.	Temperature Sensors			
10.	Temperature Sensors			
11.	Temperature Sensors			
12.	Temperature Sensors			
13.	Temperature Sensors			
14.	Temperature Sensors			
15.	Temperature Sensors			
16.	Temperature Sensors			
17.	Temperature Sensors			
18.	RTD Sensor (Inbuilt)			

Calibration Certificate has been attached as **Annexure-02**.



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 7 of 19

5.0 System / Equipment Description

5.1 System / Equipment details

The BOD Incubator will be used to Incubate the test samples at temperature 22.5 °C.

5.2 System /Equipment Identification

Component	Specifications
Name of equipment	BOD incubator
Model	
Serial Number	
Tag No.	
Name of the Supplier	
Chamber size	900 mm (H) x 600 mm (W) x 600 mm (D)
Temperature range	10 to 60°C
Temperature display	Digital with readability of 0.1°C
Trays	3 Nos. - Perforated
Tray Size	560 x 560 mm
Door	Double wall metal door, magnetic gasket and lock
Chamber Heating	By Tubular heater with Stainless Steel fins
Chamber Cooling	Using Hermetically sealed compressor coupled with evaporation coil and fan cooled condenser in a removable tray at the bottom of the equipment.
Controller	Programmable Logic Controller (PLC)
PLC Model No.	
Human Machine Interface (HMI)	
Control Panel	Panel at front top to view and set temp. real time clock
Temperature sensor	PT 100 type, Make Simplicon
Equipment Location	Microbiology laboratory (QA/QC Block)
Material of Construction	
Internal Chamber	SS 304
External Chamber	SS 304
Trays	SS 304
Insulation	PUF insulation between outer chamber and inner chamber



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 8 of 19

6.0 Temperature Mapping Procedure

The following procedure has been used for temperature mapping of BOD Incubator.

- 6.1 Location of temperature sensors in chambers was as shown in the diagram given in **Exhibit – E01**.
- 6.2 16 No. of sensors were used for the temperature mapping
- 6.3 One sensor was placed at each corner of each shelf and one in the middle.
- 6.4 One sensor was placed parallel to the inbuilt sensor.
- 6.5 The recording / printing interval was set as 30 Minutes in data loggers.
- 6.6 Closed the door of Incubator and started the temperature recording.
- 6.7 Recorded the temperature profile of the equipment for 24 hours.
- 6.8 The print out of the data was taken and has been attached along with the report as **Annexure-03**.
- 6.9 Observations of the temperature mapping have been recorded as per **Exhibit – E02**.
- 6.10 **Acceptable criteria:** Temperature variation at different locations shall not be more than $22.5 \pm 2.0^{\circ}\text{C}$.
- 6.11 No deviation was observed during Temperature mapping study.

7.0 Acceptance Criteria

Temperature mapping will be considered acceptable when requirements listed in section 6.0 of this protocol has been fulfilled and BOD Incubator is performing as per intended purpose.

8.0 Summary and Conclusion

Based on temperature mapping data (24 hours) of BOD Incubator (Equipment No.:) in BET/MLT lab in Microbiology lab it is evident that the temperature is maintained as per the acceptance criteria. The mapping activity was carried out by putting 16 probes (Refer Section 6.0) which is found consistent.

Hence the temperature mapping activity stands validated and BOD Incubator can be used for the routine testing.

9.0 Approval of Qualification Report

The temperature mapping report has been evaluated and finally approved by Head Quality Assurance.



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 10 of 19

10.0 Observed Deviation

S.No.	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective action taken and justification given by	

Report Approved By

Department Head

Quality Head



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 13 of 19

11.0 List of Exhibits / Annexure

11.1 List of Exhibits

Exhibit No.	Exhibit Title	No. of Pages
E01	Diagram Showing Locations of temperature probes in BOD Incubator	
E02	Temperature mapping record	
Total No. of Pages		

11.2 List of Annexure

Annexure No.	Annexure Title	No. of Pages
01	Training Record	
02	Calibration certificates	
03	Printouts of Data logger	
Total No. of Pages		

12.0 Reference Documents (If Any)

NA



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

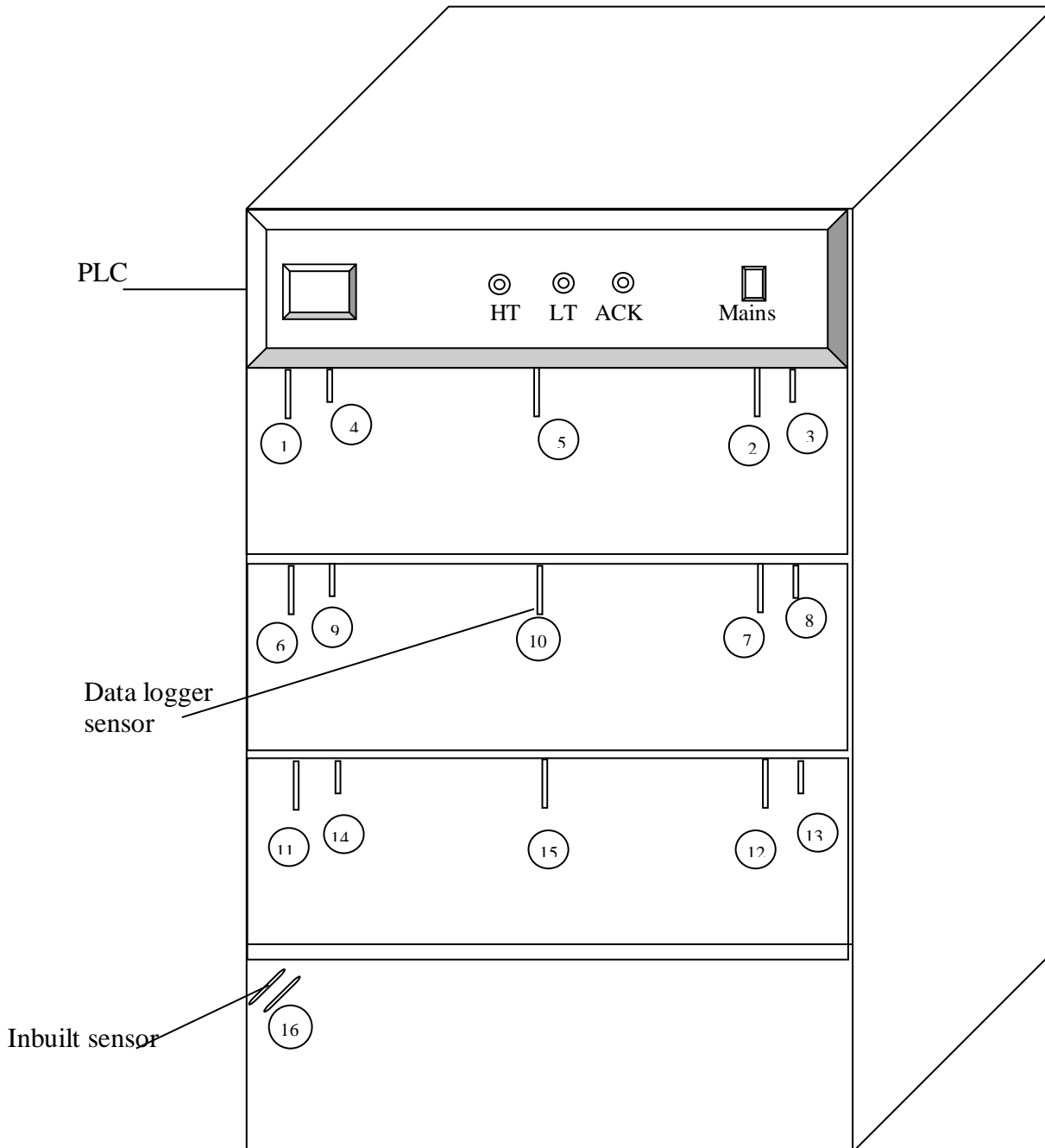
REPORT No.:

REVISION No.:

PAGE No.: 1 of 19

Exhibit – E01

Diagram Showing Locations of Temperature Probes in BOD Incubator



1 to 16 No. is sensors of External data logger.

Checked By: _____
(QC) (Name)

(Sign)

(Date)

Verified By: _____
(QA) (Name)

(Sign)

(Date)



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 1 of 19

Exhibit – E02

Temperature Mapping Record

Mapping started on :

Set Temperature (°C):

Holding time started at/date:

Holding time ended at/date:

Probe Description	Minimum Temperature (°C)	Maximum Temperature (°C)	Average Temperature (°C)	Remarks
Probe 1				
Probe 2				
Probe 3				
Probe 4				
Probe 5				
Probe 6				
Probe 7				
Probe 8				
Probe 9				
Probe 10				
Probe 11				
Probe 12				
Probe 13				
Probe 14				
Probe 15				
Probe 16				

Acceptance Criteria – Temperature at any location shall not show variation more than 22.5 ± 2 °C.

Remarks: Temperature at all the locations **is within/is not within** acceptance criteria.

Checked By: _____
(QC) (Name) (Sign) (Date)

Verified By: _____
(QA) (Name) (Sign) (Date)



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 2 of 19

Annexure – 01

Training Record

Equipment Name:	BOD Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 3 of 19

Annexure – 02

Calibration Certificates

Equipment Name:	BOD Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	



**TEMPERATURE MAPPING
REPORT
FOR
BOD INCUBATOR**

PROTOCOL No.:

REVISION No.:

REPORT No.:

REVISION No.:

PAGE No.: 4 of 19

Annexure – 03

Print outs of Data logger

Equipment Name:	BOD Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	