



**TEMPERATURE MAPPING REPORT
FOR
REFRIGERATOR**

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**REPORT
FOR
TEMPERATURE MAPPING
OF
REFRIGERATOR**

AREA: MICROBIOLOGY LAB (QA/QC BLOCK)

LOCATION: BET/MLT LAB

Document No.	RPT/TM/ QB/RFG/001/03
Supersedes	RPT/TM/ QB/RFG/001/02
Ref. Protocol No.	PRT/TM/ QB/RFG/001/03
Date of Final Approval	
No. of Pages	



PARABOLIC DRUGS LTD.

Village Sundhran, Tehsil Derabassi, District Mohali, Punjab (India)



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1.0 Report Approval

This is a specific report for Temperature Mapping of Refrigerator, 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



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2.0 Overview

2.1 Objective

To establish the methodology for temperature mapping of Refrigerator (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 Refrigerator (Equipment No.:) has been qualified to ensure uniformity of temperature at different locations for storage of the samples and other material.

This report is applicable for the temperature mapping of the Refrigerator (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



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3.0 Training Record

3.1 Purpose

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

3.2 Scope

This Training is applicable to the temperature mapping procedure of the Refrigerator, 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.*



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4.0 Pre – Qualification Requirements

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

S.No.	Instrument Name	Instrument Code / Sr. 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			

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



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5.0 System / Equipment Description:

5.1 System / Equipment details:

The Refrigerator shall be used for the safe storage of the cultures, BET reagents and media at temperature 2-8°C as well as at temperature below -15° C.

5.2 System /Equipment Identification:

Component	Specifications
Name of equipment	Refrigerator
Make	LG
Model	
Serial Number	
Tag No.	
Colour	Bright Silver
Chamber size	1832 mm (H) x 640 mm (W) x 705 mm (D)
Capacity	390 Litres
No. of Door	2 Nos.
Equipment Location	Microbiology laboratory (QA/QC Block)



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6.0 Temperature Mapping Procedure

The following procedure has been used for temperature mapping of Refrigerator.

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 The recording / printing interval was set as 30 Minutes in data loggers.

6.4 Closed the door of the Refrigerator and started the temperature recording.

6.5 The temperature profile of the refrigerator was recorded for 24 hours.

6.6 The print out of the data was taken and has been attached along with the report as **Annexure-03**.

6.7 Observations of the temperature mapping have been recorded as per **Exhibit – E02**.

6.8 Acceptable criteria:

- De-freezer : NMT -15°C
- Lower Chamber: 2-8° C

6.9 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 Refrigerator is performing as per intended purpose.

8.0 Summary and Conclusion

Based on temperature mapping data (24 hours) of Refrigerator (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 Refrigerator can be used for the routine use.

9.0 Approval of Qualification Report

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



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10.0 Observed Deviation

Sr. 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				



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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 Refrigerator	
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

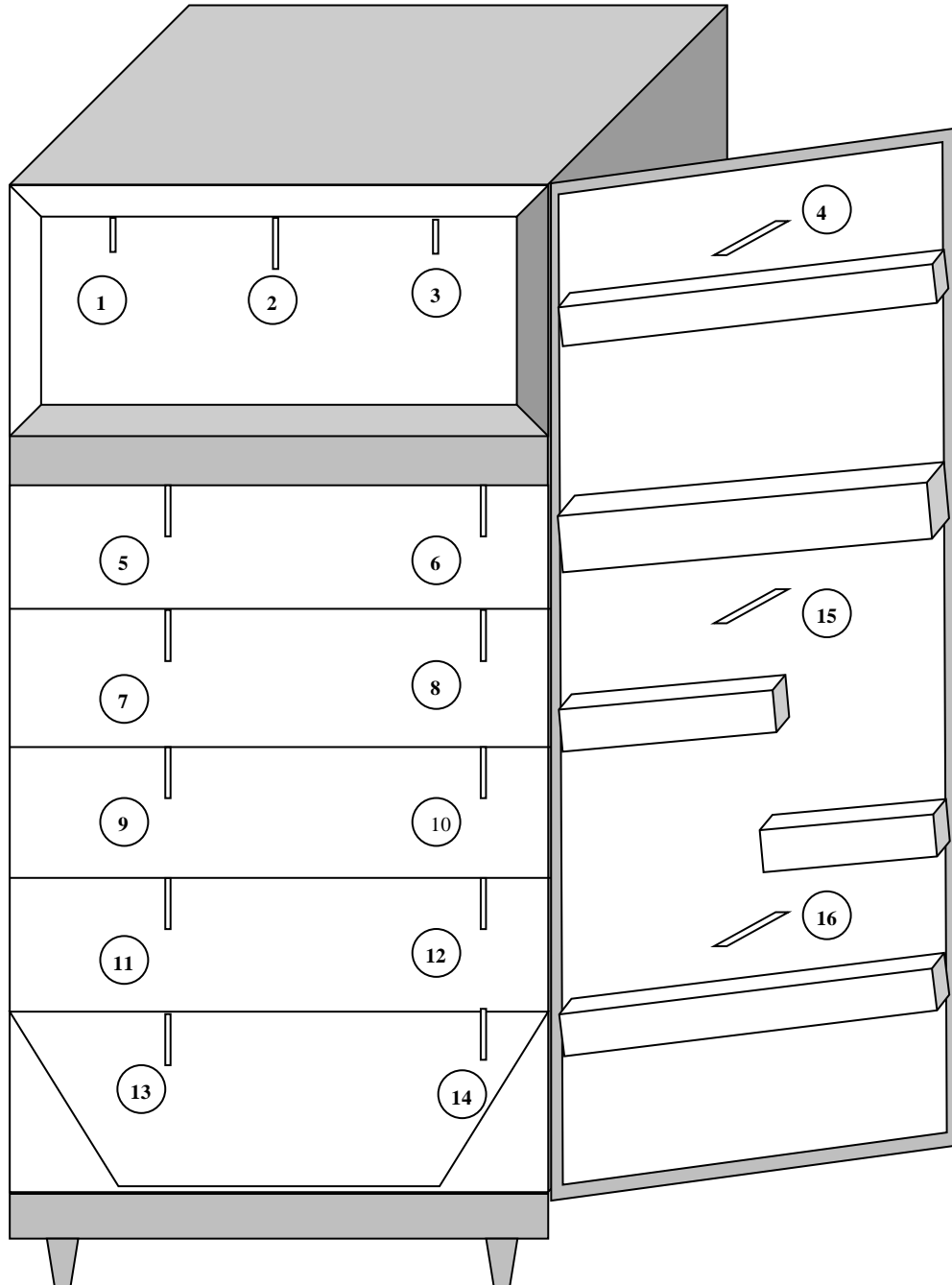


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Exhibit – E01

Diagram Showing Locations of Temperature Probes in Refrigerator



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

Checked By: _____
(QC) (Name)

(Sign)

(Date)

Verified By: _____
(QA) (Name)

(Sign)

(Date)



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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 –

- De-freezer : NMT -15 °C
- Lower Chamber : 2-8 °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)



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**Annexure – 01
Training Record**

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



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**Annexure – 02
Calibration Certificates**

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



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Annexure – 03

Print outs of Data logger

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