



**TEMPERATURE MAPPING
REPORT
FOR
COLD CHAMBER**

PROTOCOL No.:

REVISION No.:

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EQUIPMENT ID. No.

LOCATION

DATE OF QUALIFICATION

SUPERSEDES PROTOCOL No.

Approved RM area

Nil



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1.0 REPORT PRE- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The report covers all aspects of Temperature Mapping for the Cold Chamber, installed in approved RM area.
- This report will define the methods and documentation used to qualify Cold Chamber for Temperature Mapping.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Approval and Compilation of the Temperature Mapping Report.• Co-ordination with Quality Control and Engineering to carryout Temperature Mapping Activity.• Monitoring of Temperature Mapping.• Post Approval of Temperature Mapping Report after Execution.
Warehouse	<ul style="list-style-type: none">• Pre Approval of Temperature Mapping Report.• Post Approval of Temperature Mapping Report after Execution.
Engineering	<ul style="list-style-type: none">• Reviewing of Temperature Mapping Report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & Preventive Maintenance as per schedule.• Post Approval of Temperature Mapping Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Cold Chamber
Equipment
Manufacturer's Name	Voltas
Location of Performance	Approved RM area



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7.0 MASTER DOCUMENT VERIFICATION FOR AREA :

S.No.	Description of Control	Document Ref. No.	Status / Remarks
1.	Verify all the Calibration Certificates of Used Data Loggers (For Empty)		
	Verify all the Calibration Certificates of Used Data Loggers (For Loaded)		
2.	Verify the procedure of Protocol		



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7.1 TEMPERATURE MAPPING DETAILS FOR EMPTY CONDITION:

Name of Equipment	
Equipment ID No.	
Date of Monitoring	
Recording Frequency	
Condition	

7.2 DATA LOGGER CALIBRATION STATUS :

S.No.	Data Logger ID No.	Calibration Certificate No.	Calibration Done Date	Calibration Due Date
1.0				
2.0				
3.0				
4.0				
5.0				
6.0				
7.0				
8.0				

Verified By:
(Quality Assurance)
Sign / Date.....

Inference:.....
.....
.....

Reviewed By:
(Quality Assurance)
Sign & Date.....



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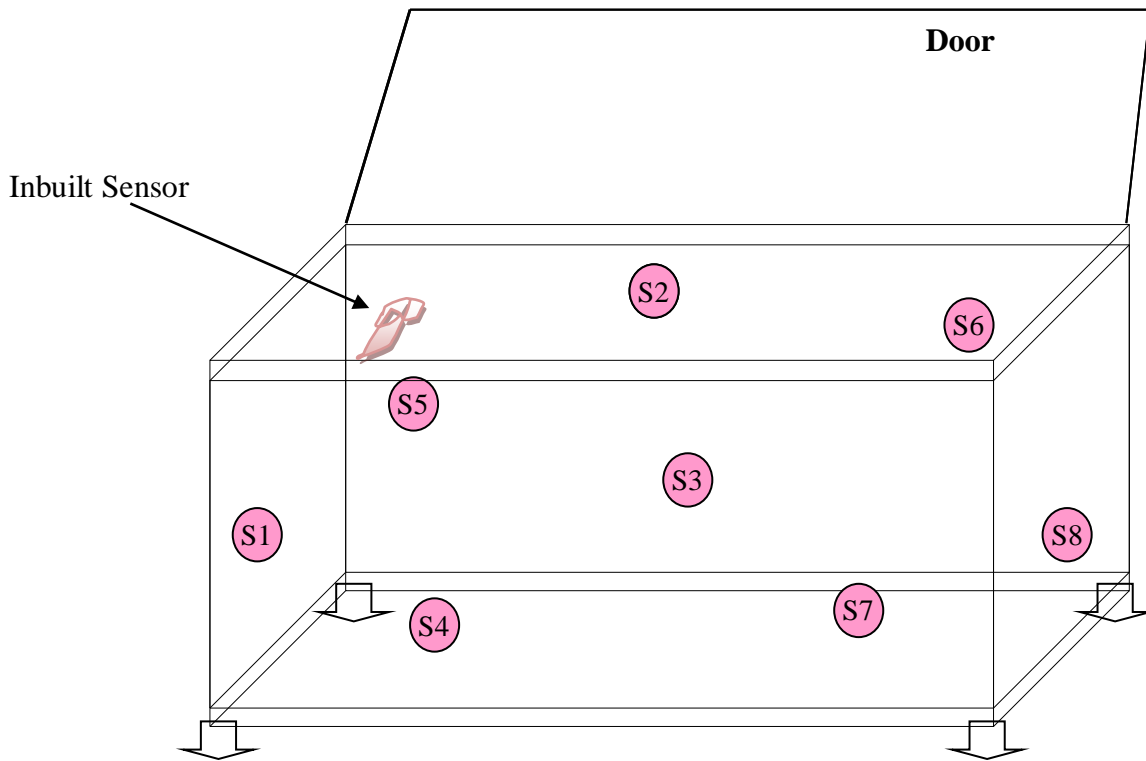
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Figure 1: Sensor Location Layout of Temperature Mapping In Cold Chamber Empty Condition





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7.3 Observation Report for (Empty condition):

S.No.	Data Logger ID No	Observation			
		Minimum	Maximum	Average	MKT(°C)
		Temp. (°C)	Temp. (°C)	Temp. (°C)	Temp. (°C)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

Verified By:

(Quality Assurance)

Sign / Date.....

Inference:.....

.....

.....

Reviewed By:

(Quality Assurance)

Sign & Date.....



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7.4 TEMPERATURE MAPPING DETAILS FOR LOADED CONDITION:

Name of Equipment	
Equipment ID No.	
Date of Monitoring	
Recording Frequency	
Condition	

7.5 DATA LOGGER CALIBRATION STATUS :

S.No.	Data Logger ID No.	Calibration Certificate No.	Calibration Done Date	Calibration Due Date
1.0				
2.0				
3.0				
4.0				
5.0				
6.0				
7.0				
8.0				

Verified By:
(Quality Assurance)
Sign / Date.....

Inference:.....
.....
.....

Reviewed By:
(Quality Assurance)
Sign & Date.....



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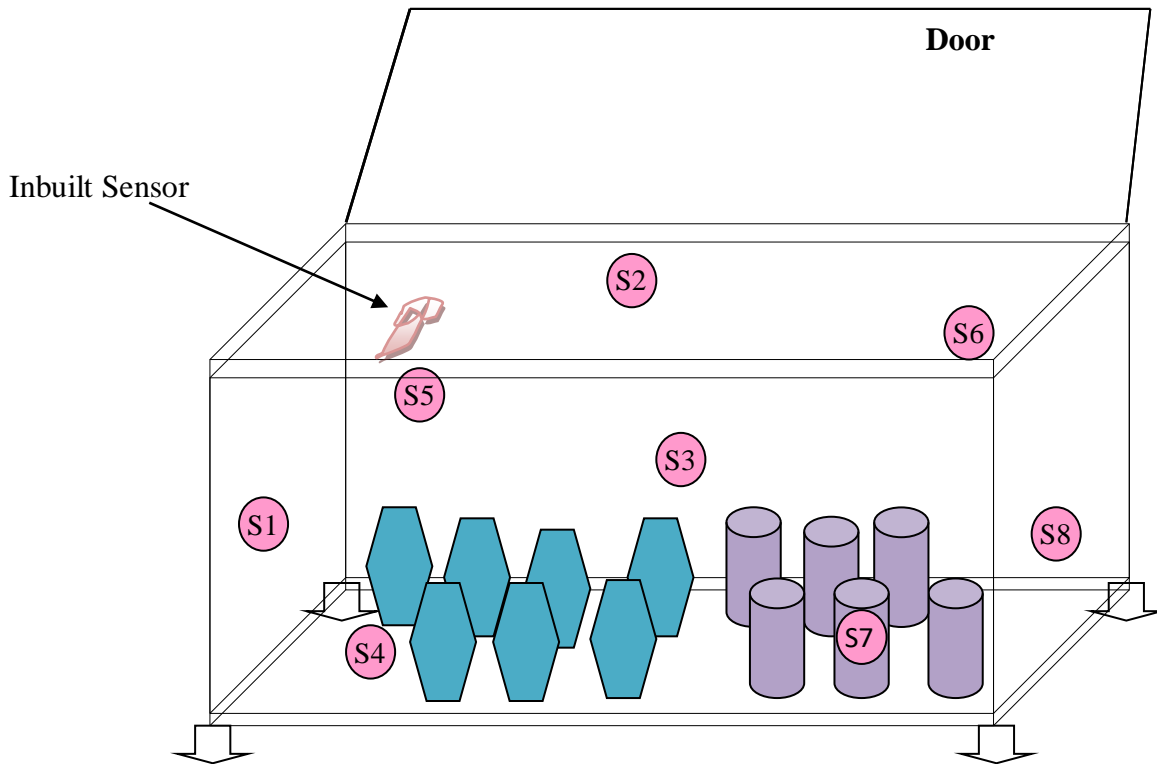
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Figure 1: Sensor Location Layout of Temperature Mapping In Cold Chamber Loaded Condition





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7.6 Observation Report for (Loaded condition):

S.No.	Data Logger ID No	Observation			
		Minimum	Maximum	Average	MKT(°C)
		Temp. (°C)	Temp. (°C)	Temp. (°C)	Temp. (°C)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

Verified By:

(Quality Assurance)

Sign / Date.....

Inference:.....

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Mean Kinetic Temperature:

$$T_k = \frac{.H/R}{-\ln \frac{e^{-H/RT_{(1)}} + e^{-H/RT_{(2)}} + \dots + e^{-H/RT_{(n)}}}{n}}$$

- T_k = Mean Kinetic Temperature
- .H = the activation energy which is a constant of 9982.68
- R = the universal gas constant
- T = the temperature in degrees K (i.e. °C + 273.1)
- n = the total number of (equal) time periods over which data are collected
- e = the natural log base

Application of this formula is more straight forward than it appears. T₍₁₎ is the average temperature recorded over the first time period, T₍₂₎ is the average temperature recorded over the second time period etc. to the nth time period.

Verified By:
(Quality Assurance)
Sign / Date.....

Inference:.....
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Reviewed By:
(Quality Assurance)
Sign & Date.....



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8.0 REFERENCES

The Principle Reference is the following:

- WHO Technical Report Series No. 961, 2011.
- Guidelines on good distribution practice of medicinal products for human use (94/C 63/03).
- USP Chapter 1079 Monitoring Devices- Good Storage and Shipping Practices.
- USP Chapter 1118 Monitoring Devices- Time, Temperature and Humidity.

9.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates for Data Logger.
- Data sheet generated through Temperature mapping

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

+ve	:	Positive
cGMP	:	Current Good Manufacturing Practices
TMR	:	Temperature Mapping Report
ID.	:	Identification
mm	:	Mili meter
MOC	:	Material of Construction
NLT	:	Not Less Than
Nos.	:	Numbers
PQ	:	Temperature Mapping
S	:	Sensor
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
Temp.	:	Temperature
WHO	:	World Health Organization

17.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By



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18.0 REPORT POST- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			