TEMPERATURE MAPPING PROTOCOL FOR COLD CHAMBER

EQUIPMENT ID. No.	
LOCATION	Approved RM area
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**Nil**

PROTOCOL CONTENTS

1.0 PROTOCOL- 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)			

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 Protocol covers all aspects of Temperature mapping for the Cold chamber, installed Approved RM area.
- This Protocol will define the methods and documentation used to qualify Cold Chamber for Temperature mapping.

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 Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation Review & Authorization of the Temperature Mapping Protocol. • Co-ordination with Quality Control and Engineering to carryout Temperature Mapping Protocol. • Monitoring of Temperature Mapping Activity.
Warehouse	• Approval of Temperature Mapping Protocol. • To Co-ordinate and support for Execution of Temperature Mapping study as per Protocol.
Engineering	• Review & Approval of Temperature Mapping Protocol. • Co-ordination, Execution and technical support in Cold Chamber Temperature Mapping Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Cold Chamber
Equipment ID	……..
Manufacturer's Name	Voltas
Location	Approved RM area

6.0 REASON FOR VALIDATION:

New Equipment Installed in Approved RM area.

7.0 SITE OF STUDY:

- Approved RM area.

8.0 PRE-REQUIREMENT:

8.1 Training:

Training shall be provided for the entire concerned Person involved in Temperature activity. And record in Temperature mapping Report.

8.2 Instrument Calibration:

- Verify all the Calibration Certificates of Used Data Loggers.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of **Cold Chamber**.
- Preparation of SOP for Preventive Maintenance of **Cold Chamber**.

8.3 TEST EQUIPMENT:

S.No.	Test Instrument
1.	Calibrated 8 Data logger.

9.0 METHODOLOGY:

9.1 SYSTEM DESCRIPTION:

- Standard Cold chamber is a jacketed chamber containing cooling coils and a fan inside the chamber to evenly distributing cooling. The temperature of the chamber increases and reaches to the set point temperature, the control system in place, controls this temperature.
- Cold chamber is used for store of heat sensitive products.

9.2 TESTS AND CHECKS:

9.2.1 (LOADED CHAMBER):

9.2.1.1 OBJECTIVE

- To ensure that the Cold chamber when operated with Load chamber is capable of producing the temperature profiles as per the temperature set points set in the equipment.
- Three run shall be performed to qualify the measurement of the temperature throughout the Chamber by Data Loggers

9.2.2 EQUIPMENT REQUIRED

- Calibrated 8 Data Logger.

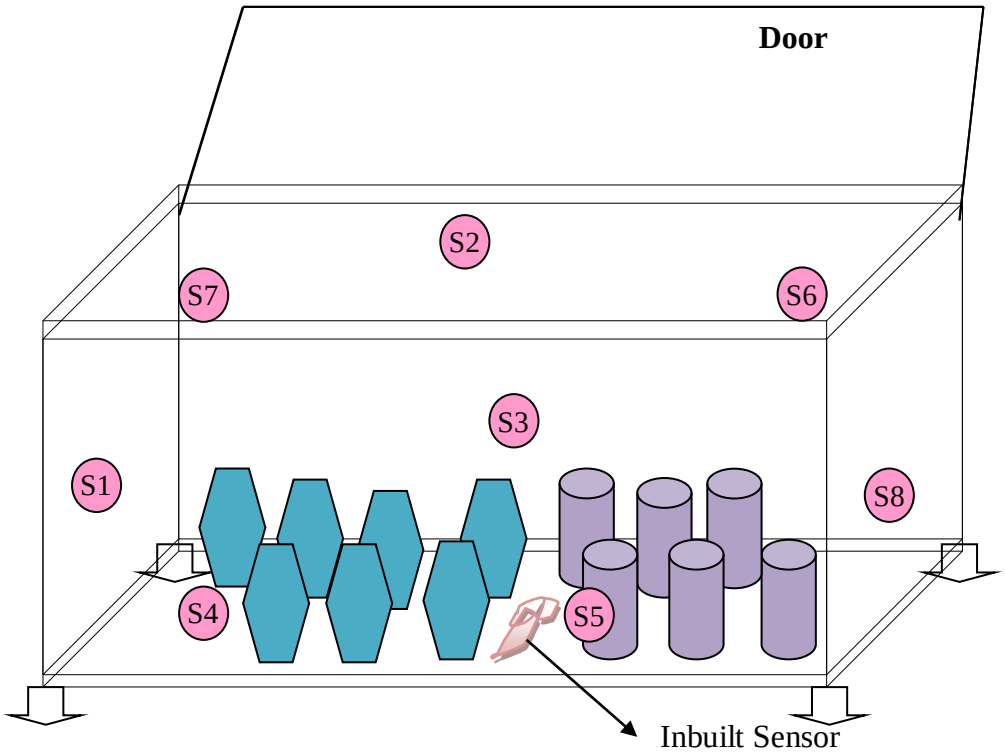
9.2.3 PROCEDURE FOR MAPPING :

- Before starting with the temperature mapping ensures that all the instruments used for the mapping are calibrated, check that all utilities as per installation qualification on are provided properly and reference certificates are available. Attach the calibration certificates with the temperature mapping report.
- Set the temperature of data logger 2°C to 8°C to be operated during the test
- Set the frequency of data logging as 5 minutes and affix data loggers in the area in such a manner that geometrically covers the whole area of equipment (which is also mentioned respective figure-1).
- Start the temperature mapping and continue the study for 72 hours with data logger recording frequency of 5 minute interval.
- Place the 8 data loggers at defined positions in as per figure-1 for continue the Temperature mapping study for 72 hours., hang the data loggers at different positions and different heights in Cold chamber, After completion of temperature mapping, take the print out of the recorded data by the connecting with software and start the compilation of obtained data & calculate the mean kinetic (MKT).
- Attach the raw data of observed value of temperature during study with temperature mapping report along with trends study and calibration certificates of the used data loggers.
- Location of Data logger is given in the Empty & Load condition Table-1 & Figure-1.

Table 1: Location of Temperature Sensors inside the Chamber

Sensor No.	Location in the Chamber
S1	In middle Left front of Chamber
S2	Top middle in near door backside of chamber
S3	Bottom middle backside of Chamber
S4	In Left Bottom front of chamber
S5	Middle Left backside of Chamber
S6	Top right backside of chamber
S7	Bottom right front of Chamber
S8	Bottom right backside of chamber

Figure 2: Schematic Diagram of Thermocouples in Cold chamber Load Condition



9.3 Selection Criteria:

- Data Logger should be arranged in a grid fashion along the width and length of the Cold chamber so that the chamber is reasonably covered, with data logger.
- Mentioned locations for placement of data loggers are evaluated by the considering of different- Different factors on the basis of critical location selection such as area dimension arrangements,
- Data Loggers should be cover as all the upper & lower side of Freezer, & center Freezer.

- A mapping study establishes the Temperature distribution within the zone being mapped and it locates cold point.

10.0 ACCEPTANCE CRITERIA

- The study shall be perform in Loaded Condition.
- In Cold chamber all the placed data loggers should be maintain with-in 2°C to 8°C throughout the duration of Temperature mapping.
- Calculated MKT value should come temperature limit 2°C to 8°C with-in specified criteria at all the placed locations.

11.0 VALIDATION/REVALIDATION CRITERIA:

- Major modification in the existing equipment/utility/area (in terms of change in area dimension).
- During monitoring if system is found to be malfunctioning.

12.0 FREQUENCY OF VALIDATION:

- After any major breakdown or after major modification.
- After Change of Location.
- Once in 2year ±1 month.

13.0 REFERENCES:

- WHO Technical Report Series No. 961, 2011.

14.0 DOCUMENTS TO BE ATTACHED:

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

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during Temperature mapping, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.

- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an
- Impact on properties of product & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during Temperature mapping, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an
- Impact on properties of product & prepare final conclusion.

18.0 ABBREVIATIONS:

+ve	:	Positive
cGMP	:	Current Good Manufacturing Practices
TMP	:	Temperature Mapping Protocol
ID.	:	Identification
ºC	:	Degree Centigrade
mm	:	Mili meter
NLT	:	Not Less Than
Nos.	:	Numbers
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
Temp.	:	Temperature
-ve	:	Negative
WHO	:	World Health Organization

19.0 REVISION HISTORY:

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