Temperature mapping of storage areas

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products

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Acknowledgments

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Contents

Abbreviations

3PL	Third Party Logistics (provider)
CAPA	Corrective and Preventive Action (procedures)
GMP	Good Manufacturing Practice
IQ	Installation Qualification
NIST	National Institute of Standards and Technology (US)
SLA	Service Level Agreement
SOP	Standard Operating Procedure
EDLM	Electronic Data Logging Monitor
TTSPP	Time and Temperature-Sensitive Pharmaceutical Product

Glossary

Component: Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a standalone unit (valves, switches, etc.).

Controller: A device that interprets a mechanical, digital or analogue signal, generated by a sensor, to control an equipment or component.

Deviation: Any discrepancy between the protocol and the actual performed test, test function methodology, testing equipment, testing material etc.

Installation qualification (IQ): The process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with the operational instructions.

Instrument: A device that interprets a mechanical, digital or analogue signal generated by a sensor, and converts it into engineering units (°C, % RH, mA, etc.) through scaling.

Key Operating Parameters: parameters that must be maintained in order to process or produce products with consistent quality attributes and those that may have an impact on the proper operation of the equipment.

Main equipment: Major equipment to be qualified.

Mapping: Documented testing that demonstrates with a high degree of assurance that a specific process will meet its pre-determined acceptance criteria.

Operational qualification (OQ): Documented verification under controlled conditions that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges.[1]

Performance Qualification (PQ): Documented verification that that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications.[2]

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. It does not, however, include medical devices[3].

Refrigeration equipment: The term 'refrigeration' or 'refrigeration equipment' means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

Sensor: A mechanical device (pressure switch, bimetal temperature switch, etc.), or a digital or analogue transducer (limit switch, pressure sensor, temperature sensor, etc.)

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[1] PDA Technical Report No. 39: Guidance for Temperature Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment, 2007.

[2] ibid

[3] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments*.

that generates a mechanical or electrical signal to an instrument or a controller in order to be interpreted.

Service Level Agreement (SLA): A service level agreement or contract is a negotiated agreement between the customer and service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can either be legally binding, or an information agreement. The SLA may also specify the target and minimum level performance, operation or other service attributes[4].

Standard Operating Procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Storage temperature: The temperature range listed on the TTSPP label, and within the regulatory filings, for long-term storage.

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise pre-defined limits.

Time and temperature sensitive pharmaceutical product (TTSPP): Any pharmaceutical good or product which, when not stored or transported within pre-defined environmental conditions and/or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

Validation: Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria.[5]

[4] Definition from IATA, Chapter 17, 9th Edition, June 2009.
[5] PDA Technical Report No. 39: *Guidance for Temperature Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment*, 2007.

1. Introduction

This technical supplement has been written to amplify the recommendations given in Section 4.7 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*[6]. The purpose of a temperature mapping study is to document and control the temperature distribution within a storage area.

This document describes how to carry out a systematic mapping procedure in any cold room, freezer rooms or other temperature-controlled store. It does not cover mapping of small scale cold chain equipment such as refrigerators of freezers. Generally speaking, these products are independently tested and prequalified for the storage of TTSPPs, although it is still important that the equipment is correctly installed and operated[7].

The following Technical Supplements are also relevant:

- *Calibration of temperature control and monitoring devices.*
- *Qualification of temperature-controlled road vehicles.*
- *Qualification of temperature-controlled storage areas.*
- *Temperature and humidity monitoring systems for transport operations.*

1.1 Requirements

All new temperature-controlled storage areas must be temperature-mapped as part of a fully documented verification process, before the installation is commissioned and handed over by the installer. Until this has been done, it is not safe to store TTSPPs in such areas. The temperature mapping procedures should:

- Demonstrate the air temperature profile throughout the storage area, when empty and in a normal loaded condition;
- Define zones which should not be used for storage of TTSPPs (for example areas in close proximity to cooling coils, cold air streams or heat sources); and
- Demonstrate the time taken for temperatures to exceed the designated limits in the event of power failure.

Subsequent mapping exercises must also be carried out on a periodic basis – for example, every three years – in order to demonstrate continuing compliance. In addition mapping should be carried out whenever significant modifications are made to the store. Examples include changes in the pattern of use that may increase loading or affect air circulation, or changes to the refrigeration equipment, such as an alteration to the set point. Finally a re-mapping exercise may be justified whenever an analysis of temperature and/or humidity monitoring records show unexplained variability outside normal operating limits.

All mapping exercises should be fully documented in order to demonstrate compliance to management, clients and the regulatory authorities.

[6] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf
[7] See for example: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

1.2 Objectives

The objective of the Technical Supplement is to provide clear guidance on how to conduct a temperature mapping study in a temperature-controlled storage area. This guidance applies to any space designed for long-term or short-term storage of TTSPPs or other temperature-sensitive products.

1.3 Target readership

This document is relevant to wholesalers, warehouse operators, distributors, dispatchers and 3PLs who store and distribute TTSPPs. The specific target audience within these organizations includes those who have direct responsibility for quality management, for example, Quality Assurance (QA) Managers and Operations Managers.

2. Guidance

A temperature mapping exercise is required for any space allocated for the storage and handling of products with a specified labelled storage temperature. This includes freezer rooms, cold rooms, temperature-controlled storage areas, quarantine areas and receiving and loading bays. It may also include laboratories. The permitted temperature ranges in these areas will vary – for example: -25°C to -10°C, 2°C to 8°C, 15°C to 25°C, etc. Temperature mapping may also need to be carried out in spaces without active temperature control.

A mapping study establishes the temperature distribution within the zone being mapped and it locates hot and cold spots. The collected data provides an essential source of information to ensure that all TTSPPs are correctly stored within their labelled temperature range(s). Mapping may also be used to identify zones where remedial action needs to be taken; for example by altering existing air distribution to eliminate hot and cold spots, or by retro-fitting new air distribution equipment to reduce temperature stratification in high-bay warehouses[8] .

A temperature mapping exercise involves a four stage process, as follows:

a. Prepare a mapping protocol.
b. Carry out the mapping exercise.
c. Prepare a mapping report.
d. Implement the recommendations by carrying out the remedial and other actions identified in the mapping report. A follow-up mapping exercise may then be needed to verify the effectiveness of the remedial actions.

2.1 Associated materials and equipment

A mapping operation requires a sufficient number of Electronic Data Logging Monitors (EDLMs) to ensure that the temperature distribution in the space to be mapped is adequately characterized. In addition, suitable computer equipment and software is needed to store and analyse the data. The selected EDLMs must:

- Be technically suitable for the specific mapping task and for the intended operating environment;
- Provide a reliable and continuous reliable record of time-temperature data;
- Have an appropriate temperature range so that all anticipated temperature extremes can be recorded (e.g. from -30°C to +60°C)
- Have a user-programmable data sampling period, with time intervals ranging from one minute to 15 minutes or more and sufficient memory for the intended length of the study and the chosen recording interval;
- Have a NIST- traceable 3-point calibration certificate with a guaranteed error of no more than ± 0.5°C at each calibration point.
- Allow the recorded time-temperature data to be downloaded to a computer system for subsequent analysis;

[8] High bay pallet racking stores are particularly susceptible to temperature stratification. It is essential that such stores are comprehensively mapped over their full working height.

- Have data storage and analytical software that complies with applicable regulatory requirements (21 CFR part 11)[9,10,11].

2.2 The mapping protocol

A detailed and comprehensive protocol should be prepared, reviewed and approved before the mapping exercise begins. A well-designed protocol will help ensure that the mapping study is correctly carried out. With suitable adjustments or options to cover the full range of temperature regimes, a standard protocol can be used to map any storage area in the facility.

The mapping protocol should contain the following sections:

a. Approval page and change control history.
b. Acronyms and glossary.
c. Description and rationale.
d. Scope
e. Objectives.
f. Methodology
g. Mapping report template.
h. Annexes as needed, including templates for the mapping report

The content of each of these sections is detailed below.

2.2.1 Approval page and change control history:

Include a standard template for recording approvals and changes to the document. The following is an example:

Approvals	Name	Date	Signature
Authorized by:			
Reviewed by:			
Revised by:			
Original author:			

[9] United States Pharmacopoeia: Chapter 1079: *Good Storage & Shipping Practices*.
[10] United States Pharmacopoeia: Chapter 1118: *Monitoring Devices – Time, Temperature and Humidity*.
[11] US Food & Drug Administration (FDA): *21 CFR part 11*.

Version history

No	Date	Description of change	Reason for change
1		Original	
2			
3			
4			
5			

If the protocol has been prepared by a qualified third-party, it should be authorized by the responsible person within the commissioning organization.

2.2.2 Acronyms and glossary:

Define the acronyms and technical terms used in the protocol.

2.2.3 Description and rationale

Describe the installation to be mapped and outline the reasons for carrying out the exercise.

2.2.4 Scope:

Clearly define the scope and purpose of the mapping study. The fundamental purpose is to identify temperature deviations affecting the chosen storage area(s) at the time the study is being conducted, so that remedial action can be taken. Preferably, at least two temperature mapping studies should be carried out in each area. In order to observe the effect of seasonal variation, one should be carried out during the warmest season and one during the coldest season. This will establish whether the mapped area is able to maintain stable temperatures throughout the year.

The results of the two studies can be compared so that systematic seasonally-related issues can be identified. These seasonal effects need to be separated out from any other site-specific issues arising at the times when the comparative studies are carried out.

2.2.5 Objectives:

Clearly define the detailed objectives of the study, as follows:

- Mapping temperature variations within the selected storage areas. Typically these areas include freezer rooms, cold rooms, warehouses, packing areas, loading bays and other areas in which temperature sensitive products are stored, or are temporarily held when in transit.
- Measuring temperature variations at each location within the chose area, by day of the week, and time of day.
- Documenting high and low temperature fluctuations caused by the environmental control systems operating at the time of the study – for example, heating, cooling and ventilation.
- Identifying potential airflow issues that may be the cause of temperature variations.

- Recommending where TTSPS can safely be stored in the mapped area. These recommendations should take account of any temperature deviations identified during the study as well as the approved temperature range(s) for the products being stored in the area.
- Identifying the best places to locate temperature sensors, for routine monitoring, in circumstances in which a monitoring system is installed. If a monitoring is already installed, identify the best places to re-locate temperature sensors (if necessary).
- Making recommendations for any remedial actions needed to overcome the problems identified in the study.

2.2.6 Methodology

The following steps outline the methodology for conducting a temperature mapping study.

STEP 1 – select EDLMs: Select the type of EDLM to be used. Choose a device that has sufficient memory for the intended duration of the study and the selected recording interval. As noted in Section 1.4, all loggers must have a NIST- traceable 3-point calibration completed and valid (within the current year), and have an error of no more than ± 0.5°C at each calibration point. Valid calibration certificates for each of the data loggers used in the study must be included in the mapping report. Some EDLMs with built-in batteries and a limited life are not designed to be re-calibrated; otherwise calibration should be done annually.

Calibration temperature points should be based on the required temperature range for each of the areas being studied. In general there should be one calibration point below the low end of the range, one calibration point in the middle of the range, and one calibration point above the high end of the range.

To ensure consistency, use only one type of device per mapping study. Provide a link to the manufacturer's user instructions so that those responsible for programming and reading the devices understand how to perform these actions correctly.

STEP 2 – designate the mapping team: Identify and list the team members. Record their signatures and initials so that signed records can be traced back to the person who prepared the document. Ensure that all team members receive the training needed to perform their assigned tasks.

STEP 3 – survey the site: Conduct a site survey of the area(s) to be mapped. The following information is required for each thermally separate area being mapped:

- Length, width and height dimensions.
- Drawing of each area, showing elements, such as shelving or pallet racking, that may have an effect on the even heating or cooling of the space and which may have an effect on its temperature stability. The shelving or pallet racking will be used to place the EDLMs, so it is important to record these components accurately.
- The location of heating and cooling components, including air distribution outlets and/or ceiling fans.
- The location of existing temperature recording sensors and temperature controlling sensors.

STEP 4 – establish acceptance criteria: Generally speaking the protocol should define the required acceptance criteria, based on the type of TTSPs being stored, clearly stating the temperature limits that are allowable within the area to be mapped – for example: +2°C to +8°C or +15°C to +25°C. However, some mapping studies may be performed without pre-defining any acceptance criteria. This type of study can be used to establish the types of product that can safely be stored in a specific space, and what remedial actions might have to be carried out to improve the thermal performance of the space in order to optimize its use.

STEP 5 – determine EDLM locations: Use the site survey to mark the required locations of the EDLMs. The following guidelines will help determine the number and location of the EDLMs required:

Length and width: EDLMs should be arranged in a grid fashion along the width and length of the area so that the area is reasonably covered, with EDML locations every 5-10 metres. The chosen sensor grid should take account of:

- The layout of the area (e.g., whether it is square or includes alcoves).
- The degree to which shelving and products may affect airflow.
- Where products are placed. The positions of EDLMs should coincide with locations where TTSPs are actually stored or planned to be stored. For example, it may be unnecessary to fit EDLMs in areas such as the upper part of high loading bays.
- Other considerations that may warrant more or fewer EDLMs.

Height: At each point on the grid, arrange EDLMs vertically as follows:

- If the ceiling height is 3.6 metres or less, position EDLMs directly above one another at high and low level (e.g. one EDLM at floor level, 1.2 metres and one EDLM at 3.0 metres.
- If the ceiling height is greater than 3.6 metres, arrange EDLMs in vertical arrays at the bottom, middle and top of the space. For instance, for a storage area six metres in height, three EDMLs should be positioned in each grid location heights of 1.8 metres, 3.6 metres and 5.4 metres.

Give each logger location a unique ID. It may be helpful to use a generic floor plan or diagram to decide where each logger should be positioned – see Figures 1 and 2. Figure 1 shows part of a pallet racking cold room with and adjoining temperature-controlled packing area. Figure 2 shows a small walk-in cold room.

Figure 1 – Typical location of data loggers in a pallet racking storage area

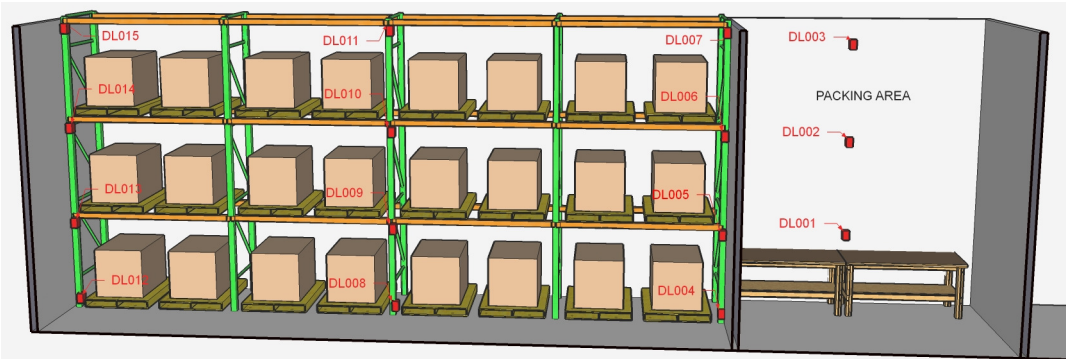
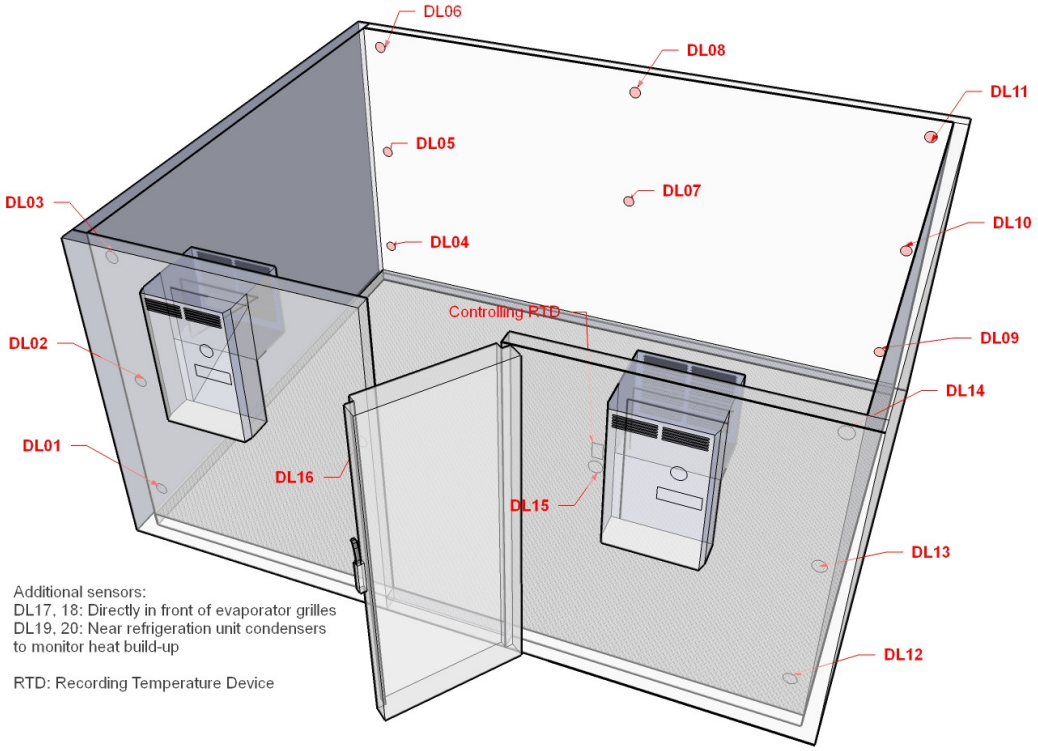


Figure 2 – Typical location of data loggers in a walk-in cold room



STEP 6 – record EDLM and thermostat locations: Record the EDLM locations on a temperature data logger location table - see example in **Annex 1.1.** Also record the location identification and set point for each thermostat in the storage area - see example in **Annex 1.2**.

STEP 7 – label and program the EDLMs: Label each EDLM with a unique ID, taken from the temperature data logger location table. Enter the manufacturer's serial number on the temperature data logger location table (**Annex 1.1)**. Recording the serial number ensures that the device can be traced to its calibration certificate. Program each device, ensuring that the recording interval is the same – typically this should be set between 5 and 15 minutes. Set the same start time for all units. This is *essential;* otherwise the downloaded readings from the individual devices cannot be time-correlated. Make sure that the start time setting gives you enough time to fix all the units in position before recording begins.

STEP 8 – fix EDLMs in position: Fix the EDLMs in position. Make sure that each one is placed exactly as shown on the temperature data logger location table and drawing. Position and fasten the devices so that they cannot be damaged or displaced during the course of routine store operations.

STEP 9 – conduct the mapping exercise: There is no formal time limit for a mapping study. Typically it should be run for a minimum of seven to 10 consecutive days for warehouses and other ambient storage areas. For temperature-controlled equipment which is not critically affected by diurnal or seasonal variations in ambient temperature (e.g. freezer rooms and cold rooms), the mapping study should be run for between 24 and 72 hours, or more if justified. If the room is fitted with duplicate refrigeration units – with or without automatic changeover – it is essential to map temperatures over a period that includes the operation of both units; preferably for a similar time period. The temperature distribution in the room may vary depending upon which system is running[12].

At the end of the study, collect the EDLMs and double-check their serial numbers and locations against the installation notes.

STEP 10 – download and consolidate the data: Download the EDLM readings and consolidate the data for the study analysis described in Section 2.4.

2.2.7 Mapping report template

The protocol should contain a template for the mapping report. This should include the sections listed below:

a. *Introduction:* a description of the objectives of the mapping study.

b. *Summary:* a summary and discussion of the results organized in the sequence set out in the mapping protocol, including a summary of deviations (if any).

c. *Conclusions and recommendations:* a general conclusion for all verifications and observations indicating the acceptability of the equipment for operation. Recommendations and remarks can be incorporated as well.

d. *Report annexes:* The report annexes should contain the following:
   - The site survey, showing EDLM locations.
   - The raw data, presented using the appropriate test data sheet format - see **Annex 1.**
   - Spreadsheet data and related temperature graphs for every EDLM used in the mapping exercise.
   - Raw results of the data analysis.
   - Key documents and notes prepared during the mapping exercise, together with any other supporting material.
   - Deviation reports, including Corrective and Preventive Actions (CAPA) forms, if required.
   - Calibration certificates for all EDLMs used.

[12] Duplicate units are sometimes set up so that one system runs most of the time and the other only cuts in at a higher temperature. This ensures that the second unit runs infrequently and therefore reduces the chances of a simultaneous breakdown.

2.3 Conducting the mapping exercise

Conduct the mapping exercise in accordance with the protocol. Ensure that all relevant personnel in the store are fully briefed so as to avoid inadvertent disruption or deactivation of the EDLMs. At the end of the study period, collect all the devices, deactivate them, and download the data for analysis.

2.4 Analyzing the data and preparing the mapping report

The mapping report should follow the general framework outlined in Section 2.2.7. The following sub-sections outline the data analysis process that precedes the writing of the report.

2.4.1 Preliminary analysis

Analyse the overall temperature stability of the study area and identify the variations that occur. Compare the measured temperatures against the acceptance criteria. The analysis of the overall temperature stability should consider factors such as:

- The ability of the environmental control systems to maintain temperatures within the acceptance criteria limits (if any).
- The overall temperature stability of the area being monitored, and the range in fluctuations it experiences over the study period.

The analysis of temperature variations should consider factors such as:

- Variations experienced by individual EDLMs.
- Temperature variations along vertical and horizontal planes, depending on the size of the area, and distribution of EDLMs.
- Temperature variations in locations close to heating and cooling components, as compared to those farthest away from these units

2.4.2 Minimum and maximum temperatures and hot and cold spots

A mapping study measures temperature fluctuations. From these data, the analyst can identify the minimum and maximum temperatures that occur in the mapped area during the study period.

Minimum temperature refers to the lowest temperature value recorded in the mapped space over the study period; maximum temperature refers to the highest value recorded during the same period. Either or both of these temperatures may be outside the specified acceptance criteria for the store. **Annex 1.3** shows a standard form that can be used to record these data, together with the mean values discussed in Section 2.4.4.

A cold spot refers to the lowest temperature value(s) recorded in the space over the study period, but with these lowest temperature value(s) remaining within the specified temperature range (e.g. cold spots identified between +15°C to +17.5°C in a room with a specified temperature range +15°C to +25°C).

A hot spot refers to the highest temperature value(s) recorded in the studied area over the study period, but with these highest temperature value(s) remaining within the specified temperature range (e.g. hot spots identified between +23°C to +25°C in a room with a specified temperature range +15°C to +25°C).

The purpose of determining hot and cold spots is to identify the locations where the monitoring system sensors should preferentially be located. Hot and cold spots need to be determined seasonally as they may be significantly different in summer and in winter.

2.4.3 Mean temperatures

Either arithmetic mean temperatures or mean kinetic temperatures (MKT)[13] can be applied to each of the separate areas being monitored over the study period. These mean temperature measurements can be useful in storage areas where the temperature fluctuates with time in a repetitive pattern (e.g. sinusoidal fluctuation, periodic peak occurrence…) and where the temperature also varies depending upon the data logger location.

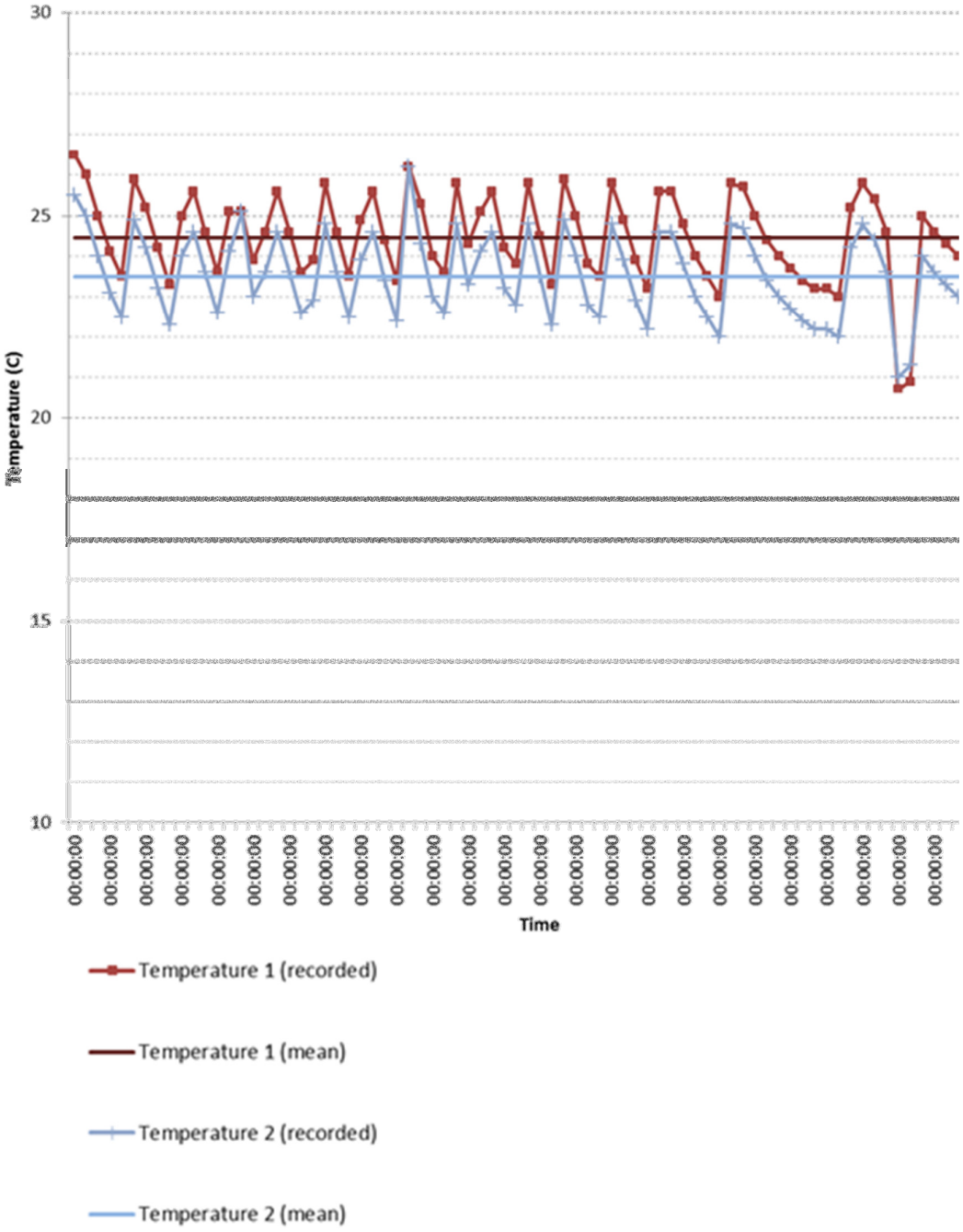
The use of mean or MKT temperatures enables the analyst to determine a mean temperature for a given EDLM location over the study period. These figures can then be compared between all the EDLM locations within the space. This enables the analyst to identify the locations where the mean temperatures are consistently lower or higher, an exercise which cannot be achieved simply by comparing individual data points.

In Figure 1, the minimum and maximum temperatures have been calculated from the data points for two locations (EDLM-1 and EDLM-2). The plot shows that the EDLM-2 location is clearly cooler on average, although there are clearly times when the two locations experience similar low and high temperatures.

Despite the usefulness of mean figures, it is essential not to disregard the actual temperature data; these figures reveal the occurrence of temperatures that are outside the specified storage temperature range.

[13] See: Seevers, R. et al. *The Use of Mean Kinetic Temperature (MKT) in the Handling, Storage and Distribution of Temperature Sensitive Pharmaceuticals*. Pharmaceutical Outsourcing, May/June 2009.

Figure 3 – Use of mean temperatures



2.4.4 *Interpreting the results and making recommendations*

This section outlines how to interpret the results, and how to use these results to support the report's recommendations:

- Document the internal temperature variations observed within the space, taking account of the EDLM reading errors specified by the device manufacturer.
- Use the data analysis to assess the overall temperature stability of the mapped space in relation to the stated acceptance criteria (if any).

- Assess the overall thermal stability of the space during the study period with specific reference to the high and low temperatures experienced[14].
- List the factors that explain the observed temperature variations. For example, the location of the heating and cooling components and doors.
- Assess consistent and inconsistent temperature variations, and fluctuations, within the space in terms of their potential impact on product storage.
- Based on the observed temperature fluctuations of mapped locations within the space, make recommendations about the optimum storage locations for highly sensitive products, and those that are less sensitive.
- Based on the observed temperature fluctuations of mapped locations within the space, make recommendations on the optimum location of the temperature sensor(s) used for routine temperature monitoring and the control sensors used to activate the heating and cooling systems.

2.4.5 Report auditing

The report content, including data sheets, results, spreadsheets and graphs should be audited and peer-reviewed by a competent independent person. The reviewer should confirm, approve and sign the major reported test and verification results and the recommendations arising from these results. If the report has been prepared by a qualified third-party, it should be approved by the person who commissioned the study.

2.5 Implementing the mapping report recommendations

The final outcome and purpose of a mapping exercise is the implementation of the report recommendations. A detailed discussion of implementation is outside the scope of this document, but it could include any of the following outcomes:

- A drawing or diagram showing where TTSPPs can safely be stored in the space that has been mapped. It is possible that there may be some zoning involved. For example, products which are not affected by freezing could be allocated to parts of a cold room where the mapping study has shown some freezing risk.
- Allocation of pallet bays to specific categories of TTSPP on the warehouse management system in order to control where stocks are positioned.
- Re-positioning of temperature monitoring sensors and/or environmental control sensors.
- Adjustment of air outlets to reduce temperature stratification and/or minimize cold and hot spots.
- Upgrading of mechanical systems to improve temperature control and performance.
- A decision to use the space for other purposes because it is unsuitable for storage of TTSPPs.

[14] Thermal stability will be affected by three main factors: the external ambient temperature; the type of building construction and the performance of the heating/cooling system. The first two factors are less significant for freezer rooms and cold rooms built inside an existing structure.

References

- United States Pharmaceopaedia: Chapter 1079: *Good Storage & Shipping Practices*.
- United States Pharmaceopaedia: Chapter 1118: *Monitoring Devices – Time, Temperature and Humidity*.
- Health Canada (HPFB Inspectorate): Guide 0069: *Guidelines for temperature Control of Drug Products during Storage and Transportation*. October 17, 2005.
- Seevers, R. et al. *The Use of Mean Kinetic Temperature (MKT) in the Handling, Storage and Distribution of Temperature Sensitive Pharmaceuticals*. Pharmaceutical Outsourcing, May/June 2009.
- US Food & Drug Administration (FDA): *21 CFR part 11.*
- WHO Technical Supplement. *Calibration of temperature control and monitoring devices.*
- WHO Technical Supplement. *Qualification of temperature-controlled road vehicles.*
- WHO Technical Supplement. *Qualification of temperature-controlled storage areas.*
- WHO Technical Supplement. *Temperature and humidity monitoring systems for transport operations.*

Annex 1 – Test data sheets

The following sections show examples of the type of data collection forms used in a mapping exercise.

A1.1 Test data sheet: temperature data logger locations

Data logger ID number	Data logger serial number	ID number on schema	Mounting ht (metres)	Description / Comments
DL-001		1	0.3	
DL-002		2	2.8	
DL-003		3	5.4	
DL-004		4	0.3	
DL-005		5	2.8	
DL-006		6	5.4	
DL-007		7	0.3	
DL-008		8	2.8	
DL-009		9	5.4	
DL-010		10	0.3	
DL-011		11	2.8	
DL-012		12	5.4	
DL-013		13	0.3	
DL-014		14	2.8	
DL-015		15	5.4	
DL-016		16	0.3	
DL-017		17	2.8	
DL-018		18	5.4	
DL-019		19	0.3	
DL-020		20	2.8	
DL-021		21	5.4	
DL-022		22	0.3	
DL-023		23	2.8	
DL-024		24	5.4	

A1.2 Test data sheet: temperature distribution

Thermostat Information		
Location	Set point	Comment
Near entrance door #1	20C	Locked
Near loading dock #4	20C	Locked

A1.3 Test data sheet: temperature distribution

Data logger ID number	Min. temp. Recorded (°C)	Max temp. Recorded (°C)	Mean temp. (°C)	Within range?		Inspected by	Date
				Yes	No		
DL-001	18.6	22.4	20.5	☒	☐	JB	
DL-002				☐	☐		
DL-003				☐	☐		
DL-004				☐	☐		
DL-005				☐	☐		
DL-006				☐	☐		
DL-007				☐	☐		
DL-008				☐	☐		
DL-009				☐	☐		
DL-010				☐	☐		
DL-011				☐	☐		
DL-012				☐	☐		
DL-013				☐	☐		
DL-014				☐	☐		
DL-015				☐	☐		
DL-016				☐	☐		
DL-017				☐	☐		
DL-018				☐	☐		
DL-019				☐	☐		
DL-020				☐	☐		
DL-021				☐	☐		
DL-022				☐	☐		
DL-023				☐	☐		
DL-024				☐	☐		
Mapping period starts at (date/hour):							
Mapping period ends at (date/hour):							
Checked by:				**Date:**			

Revision history

Date	Change summary	Reason for change	Approved