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VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

FOR

INCUBATOR

(QC-INC-04)

OF

UTOPIA PHARMACEUTICAL

10TH OF RAMADAN CITY

CLIENT:	QUALIFICATION PROVIDER:
UTOPIA THE LIFE YOU DESERVE	TAG

Package Content:

VOL-01	Performance Qualification Protocol
	Annex-01.01) Results Data Sheets
	Annex-01.02) Turn Over Package (Attachments)

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Table of Content

1. PROTOCOL REVIEW AND APPROVAL

- Prior to the initiation of qualification testing activities, this document will be issued, reviewed and approved by the appropriate personnel.
- The signatures below signify prior approval of the format and content of the final report, ensuring an accurate representation of the qualification activities planned for UTOPIA PHARMACEUTICAL.

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Name	Title	Company	Date	Signature

Change History				
No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	01/06/2025

Note: Any amendment will be indicated with italic and bold font.

CALIBRATION TAG TECHNO AIR GATE

2. INTRODUCION

2.1. Glossary/Abbreviations

- **Performance Qualification (PQ):** The process of obtaining and documenting evidence that the premises, equipment and supporting systems, as connected together, will consistently perform in accordance with the approved process method and specifications. It is the final step of qualification. In this phase, the qualification and validation team verify and document that the user requirements are verified as being met and to ensure that every part of the system will maintain a stable temperature during use.
- **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 system.
- **Controller:** A device that interprets a mechanical, digital or analogue signal, generated by a sensor, to control an equipment or component.
- **Sensor:** A mechanical device (pressure switch, bimetal temperature switch, etc.), or a digital or analogue transducer (limit switch, pressure sensor, temperature sensor, etc.) that generates a mechanical or electrical signal to an instrument or a controller in order to be interpreted.
- **Electronic data logging monitor (EDLM):** A small portable device that measures and stores temperature readings at predetermined time intervals by means of an electronic sensor. They have programmable alarm capabilities, integrated displays, and can create reports and graphs which may be permanently stored, shared and analyzed via proprietary hardware, software, desktop applications or through hosted databases.
- **TTSPP:** time- and temperature-sensitive pharmaceutical product.
- **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.
- **Mapping:** Documented measurement of the temperature distribution within a storage area, including identification of hot and cold spots.
- **Maximum Temperature:** refers to the highest value recorded in the mapped space over the study period, and it may be outside the specified acceptance criteria for the store.
- **Minimum Temperature:** refers to the lowest temperature recorded in the mapped space over the study period, and it may be outside the specified acceptance criteria for the system.
- **Mean Kinetic Temperature:** If you have a set of temperature readings across a certain period of time, the Mean Kinetic Temperature across this period means the effective average thermal value for this period. This temperature value is what the stored goods effectively feel during the mentioned time. This is not the arithmetical average of the readings.
- **Hot Spot:** refers to the highest temperature(s) recorded in the area studied over the study period, but these highest temperature(s) remain within the specified temperature range.
- **Cold Spot:** refers to the lowest temperature(s) recorded in space over the study period, but these lowest temperature(s) remain within the specified temperature range.

- **Worst Locations:** It refers to hot and cold spots determined in the space over the study period during the thermal qualification study.
  Note: It is also important to look at the overall high and low trends rather than just the highest and lowest temperatures. Average values can be useful to help confirm true hot and cold spots.

2.2. Rationale

- The rationale behind this protocol is essential for verifying the thermal performance of the Incubator located at UTOPIA PHARMACEUTICAL and to confirm that it functions as intended and produces reliable results essential for maintaining product quality and ensuring TTSPPs stored within it are maintained under appropriate conditions. By conducting performance qualification, it becomes possible to identify any deviations from the desired temperature range, reduce risks of product degradation, and maintain quality assurance measures. We aim to minimize the risk of errors or inaccuracies in testing procedures, ensuring that the system operates within specified parameters.
- Performance Qualification Protocol will provide the methodology of qualification studies, formats for recording the observation, Criteria of qualification and a guideline for documentation of the study.

2.3. Protocol Purpose

- To evaluate the heat distribution profiles and trends throughout the Incubator located at UTOPIA PHARMACEUTICAL.
- To ensure uniformity and compliance with regulatory standards and to verify that the Incubator meets regulatory requirements for temperature control.
- To identify the scope of qualification required by UTOPIA PHARMACEUTICAL.
- To determine the responsibilities of TAG and UTOPIA PHARMACEUTICAL.
- To clarify the rationale of this work scope and to clarify the rationale behind the chosen study design and its methodology.
- To describe the followed procedure used to study the heat distribution throughout the Incubator (QC-INC-04) located at UTOPIA PHARMACEUTICAL and to ensure uniformity and compliance with regulatory standards.
- To identify the personnel of charge that will perform and follow-up this scope.

2.4. Protocol Scope

The scope of this protocol covers the performance qualification of the of the Incubator (QC-INC-04) located at UTOPIA PHARMACEUTICAL for full load cycle(s) for 1 day (24 hrs.) and performing the power failure test for 30 min and open-door test for 5 min.

2.5. Documents Execution Instructions

Prior to the initiation of Performance Qualification testing activities, this document will be generated, reviewed and approved by the appropriate personnel.

The testing specified in this approved Protocol will be conducted in accordance with the instruction detailed in the test cases.

Additional documentation requirements for protocol and report are as follows:

- Each person recording or reviewing the information in this document must complete the Signature Log
- After completing entries in the test cases, the initials and date of the individual responsible for the entry must be entered in the appropriate column
- Any blank entry space or box must have a line drawn through it, initialed, and dated.
- Any correction entry must be marked with a unique line drawn through the data to be changed, initialed, and dated. After correction, wrong data must remain readable.
- General datasheets and/or supporting documentation must be inserted as near to the related test datasheet as possible and must include the following information:
  - Reference to supplemented datasheet
  - A unique id number (i.e. number of the supplemented datasheet + [a], [b], ... [aa], [ab], etc.
  - Page number
- Supporting documentation not related to a specific datasheet can be attached at the end of this document. Attachments list has to be used to assign a unique id number.
- Attachments are to be intended both as digital/magnetic and paper supported.
- When approved vendor documentation (Protocols) is available and approved by UTOPIA PHARMACEUTICAL, it will be possible to use it for the execution of the Protocol tests at the condition that the documentation meets the minimal requirements listed above.

Any test exception and failure verified during the protocol execution shall be noted on the "Deviation Report" form (Data Sheet Number 01.01.03.01 in Annex 01.01 (PQ Results Data Sheets)). Every exception and its conclusion (intended as foreseen corrective action results) shall be documented inside the related qualification summary.

2.6. Responsibilities

For the submission/approval, execution of this protocol and its final report, the responsibility of all personnel involved with the verification and documentation process are as follows:

2.6.1. COPMANY_NAME

- Provide the necessary information needed for the performance qualification protocol issue.
- Review and approve the protocol for compliance before qualification execution and ensure that the protocol aligns with regulatory requirements and company policies.
- Responsible for the operational aspects of the system being qualified.
- Provides access to the system being qualified, coordinate and assist in addressing any system-related issues that may impact the mapping process.
- Develop the project timeline and oversee the entire thermal qualification project, including planning, coordination, and execution.
- Provides any documents required in the performance qualification test such as layouts.
- Assign tasks to the responsible team members, ensure adherence to the approved protocol, and manage communication with stakeholders.
- Ensure that the thermal qualification process meets regulatory requirements and quality standards.
- Monitor data collection procedures, verify accuracy of results, and assess compliance with industry guidelines.
- Review any deviation in the deviation form, determine the corrective actions, and evaluate results of corrective measures and approve them.
- Review and approve the report and test results for compliance after execution and ensure that the report aligns with regulatory requirements and company policies.

2.6.2. TAG

- Design and prepare the qualification protocol, including all the recommendations and corrections that are required by UTOPIA PHARMACEUTICAL.
- Review and approve the protocol for compliance before qualification execution and ensure that the protocol aligns with regulatory requirements and company policies.
- Execute the qualification only after this protocol has been approved by UTOPIA PHARMACEUTICAL.
- Develop the project timeline and oversee the entire thermal qualification project, including planning, coordination, and execution.
- Assign tasks to the responsible qualified team members, ensure adherence to the approved protocol, and manages communication with stakeholders.
- Assure that any instrument used during qualification has been previously calibrated and that a copy of the calibration certificate is attached.
- Distribute the monitoring devices, ensure data collection at specified interval and troubleshoot any technical issues incident by TAG.
- Conduct and oversee the technical aspects of the thermal qualification study.
- Perform data analysis and interpret results to ensure the accuracy and reliability of the study and compare test results with the acceptance criteria and determine if it conform or not conform.
- Identify temperature trends, generate reports, and communicate findings and any deviations to UTOPIA PHARMACEUTICAL for further action.
- Assure that data from tests, executed by TAG, are properly recorded in an acceptable format on work sheet and on the report.
- Ensure that all original data, final form and tables are signed and dated, that these documents are attached to final Report or that a note with their storing location is specified.
- Ensure that the description of the tool used for tests and/or verifications, its serial number and its ID number are Reported on data collection worksheets and/or forms.
- Prepare the Performance Qualification Report including all the advices and amendments pointed out by UTOPIA PHARMACEUTICAL and submit for it for review and approval by the concerned UTOPIA PHARMACEUTICAL departments.
- Maintain records of protocol, data collection procedures, calibration certificates, and final reports and ensure that all documentation is accurate, organized, and accessible for future reference.

2.7. Signature Log

Each person records, review and approve the information in this document must complete the signature log.

2.8. System Brief Description

The scope of this protocol intends to cover the performance qualification procedure of Incubator (QC-INC-04) located at UTOPIA PHARMACEUTICAL with the following description:

System Brief Description	
Description	Incubator
Dimensions/Volume	110 Liters
Manufacturing	MEMMERT GmbH + Co.KG Germany
Model	IF110PLUS
S.N.	D420.0044
Code	QC-INC-04
Acceptance Criteria	(42 - 44) °C
Location	Incubation Room (MB-012)
Load Description	Full Load
Key Operating Parameters	Temperature

3. PERFORMANCE QUALIFICATION METHODOLOGY

3.1 Pre-Requisties

- Performance Qualification activities will only start after this Protocol is approved by the Officials deputed by UTOPIA PHARMACEUTICAL.
- After this approval, the signed original of the Report will be filed in a suitable archive dedicated to Performance qualification/validation documents while another copy will be made available for working purposes.
- This copy, in which data gathered and recorded during qualification, and to which documents (such as layout, printouts, etc.) are attached, becomes the Qualification Report for the examined system.
- Once Performance Qualification Protocol is completed, any changes shall have to be checked, planned, and approved by UTOPIA PHARMACEUTICAL and mentioned in the change history table.
- Any non-conformities encountered and any other discrepancies from acceptability criteria of this Protocol shall be recorded in the "Deviation Report" attached Data Sheet Number (Data Sheet Number 01.01.03.01 in Annex 01.01 (PQ Results Data Sheets)).

3.2 Key Concepts

- **Mean Kinetic Temperature:**

  Mean kinetic temperature (MKT) is defined by the ICH as 'A single derived temperature that, if maintained over a defined period of time, affords the same thermal challenge to a drug substance or drug product as would be experienced over a range of both higher and lower temperatures for an equivalent defined period. The mean kinetic temperature is higher than the arithmetic mean temperature and takes into account the Arrhenius equation.' The Haynes formula can be used to calculate the MKT. It is higher than the arithmetic mean and takes into account the Arrhenius equation from which Haynes derived his formula. Thus, MKT is the single calculated temperature that stimulates the non-isothermal effects of storage temperature variations.

$$T_k = \frac{\Delta H / R}{-\ln \frac{e^{-\Delta H/RT}{}_{(1)} + e^{-\Delta H/RT}{}_{(2)} + \ldots + e^{-\Delta H/RT}{}_{(n)}}{n}}$$

Where:

T_k = MKT in °K
ΔH = Heat of activation/activation energy
R = Universal gas constant (8.3144×10^{-3} kJ.Mole^{-1}. °K^{-1})
T = Temperature in °K
n = Total number of equal time periods over which data are collected

- **The intervention Tests:**

  The purpose of the door open and blackout tests in performance qualification is to simulate real-world scenarios that may impact temperature uniformity and stability within a storage environment. These tests help assess the resilience of the temperature control system and the effectiveness of the monitoring system in maintaining the required temperature conditions.

1. **Power Failure (Blackout) and Recovery Test:**
   - The blackout test involves simulating a power outage or loss for a defined period. This test evaluates the system's response to sudden temperature fluctuations and its ability to maintain temperatures within acceptable limits during an emergency situation. By conducting these tests as part of thermal mapping, organizations can ensure that their systems can withstand potential disruptions and maintain consistent temperature conditions critical for preserving product quality and compliance with regulatory standards.
   - When the mapping exercise is in progress, shut-down the power for a specific period of time and record the shut-down time, then calculate the recovery time (the maximum time after shutting down the power & turning the power on for all data loggers to get back within the acceptance limits).
   - Generally, there are no specific acceptance criteria for this test unless a recovery time is specified in the unit's manufacturer's specifications.

2. **Door Opening and Recovery Test:**
   - This test evaluates how quickly the system can recover and stabilize temperatures after a disruption. This test simulates the impact of routine door openings during operational use and assesses the system's ability to maintain temperature integrity.
   - During the mapping exercise open the door of the system for a specific period of time and record time then close the door and calculate the recovery time (the maximum time after door opening & closing for data loggers to get back within the acceptance limits).
   - The temperature should be maintained within the defined temperature limits except for a maximum of "30 minutes" following the door opening.
   - The acceptance criterion for this test is that the temperature recorded by all the EDLMs located inside the storage area should return to being within the specified temperature range within 30 minutes after the door(s) are closed at the end of the door opening test sequence.

3.3 Associated Material and Equipment Description

To ensure that the temperature distribution in the space to be mapped is adequately characterized, we should use a sufficient number of electronic data logging monitors (EDLMs) along with suitable computer equipment and software to store and analyze the data. The selected EDLMs will:

- be technically suitable for the specific mapping task and for the intended operating environment.
- provide a reliable and continuous record of time-temperature data.
- have an appropriate temperature range so that all anticipated temperature extremes can be recorded.
- have a user-programmable data sampling period, allowing time intervals to be set in the range from 1 minute to 15 minutes (maximum) and sufficient memory for the intended length of the study and the chosen recording interval.
- have a US National Institute of Standards and Technology (NIST)- traceable 3-point calibration certificate with a guaranteed error of no more than ± 0.5 °C at each calibration point.
- enable the recorded time-temperature data to be downloaded to a computer system for subsequent analysis.
- have data storage and analytical software that complies with applicable regulatory requirements (for example: 21 CFR part 11).

Used Reference Equipment Description						
Description	No. of EDLMs	Location	Accuracy	Manufacturer	Model	Calibration Due Date
Data Logger	10	Inside Incubator	± 0.5 °C	Will be determined at the execution phase		
The exact location of each data logger in Incubator is specified in the layout, see point 3.7 in this protocol.						

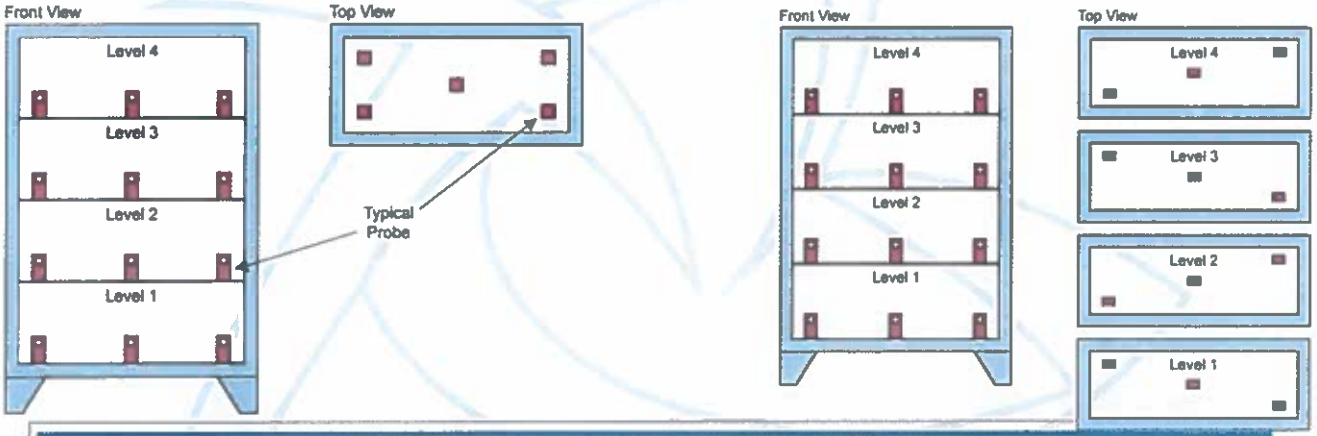
3.4 Data Loggers Quantity and Distribution Locations Rationale

By distributing data loggers at various locations within the Incubator, we can ensure that temperature remain consistent throughout it, minimizing the risk of temperature differentials that could affect products integrity.

3.4.1 Chambers/Equipment Qualification:

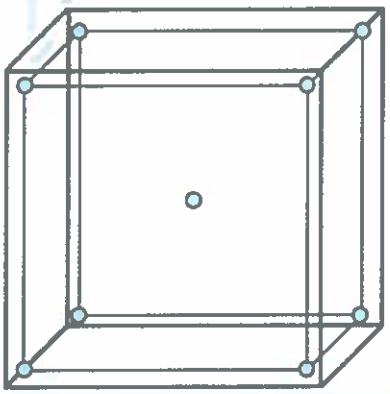
As the heat goes up and cold down the data loggers shall be placed on top and bottom shelves of the equipment. Shelving and loads may create 'hot spots' by obstructing air circulation. Due to less circulation of air in corners the data loggers shall be placed near to each corner of the equipment (As illustrated in the below figures).

- **Top Shelf:** Placing a data logger on the top shelf enables monitoring of temperature variations at the highest point within the system, where heat distribution may differ from lower levels.
- **Bottom Shelf:** Monitoring temperature at the bottom shelf helps assess heat circulation and ensures uniformity throughout the entire system space.
- **Near the Door:** Positioning a data logger near the door provides insights into temperature stability and potential impacts of external factors on the internal environment.
- **Center:** Placing a data logger in the center of the system helps evaluate overall temperature uniformity and ensures that critical samples receive consistent heat exposure.
- **Adjacent to the Heating Source:** Monitoring temperature close to the heating source allows for assessing the efficiency of heat distribution and the impact on temperature fluctuations.

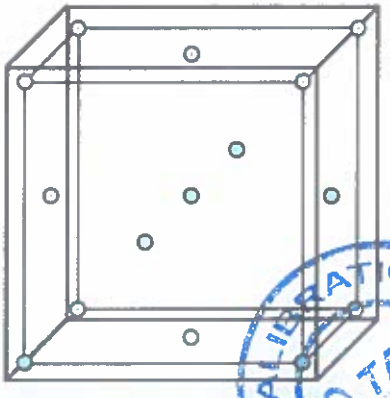


Best Practice as per ISPE and IEC Guidelines:

For Chambers up to 2 m³ (2000 L):
use 9 EDLMs (corners + center) within the usable volume of the chamber.



For Chambers up to 20 m³ (more than 2000 L):
use 15 EDLMs (corners, center, wall centers) within the usable volume of the chamber.



3.5 Procedure Description

The following steps outline the methodology for conducting the performance qualification study.

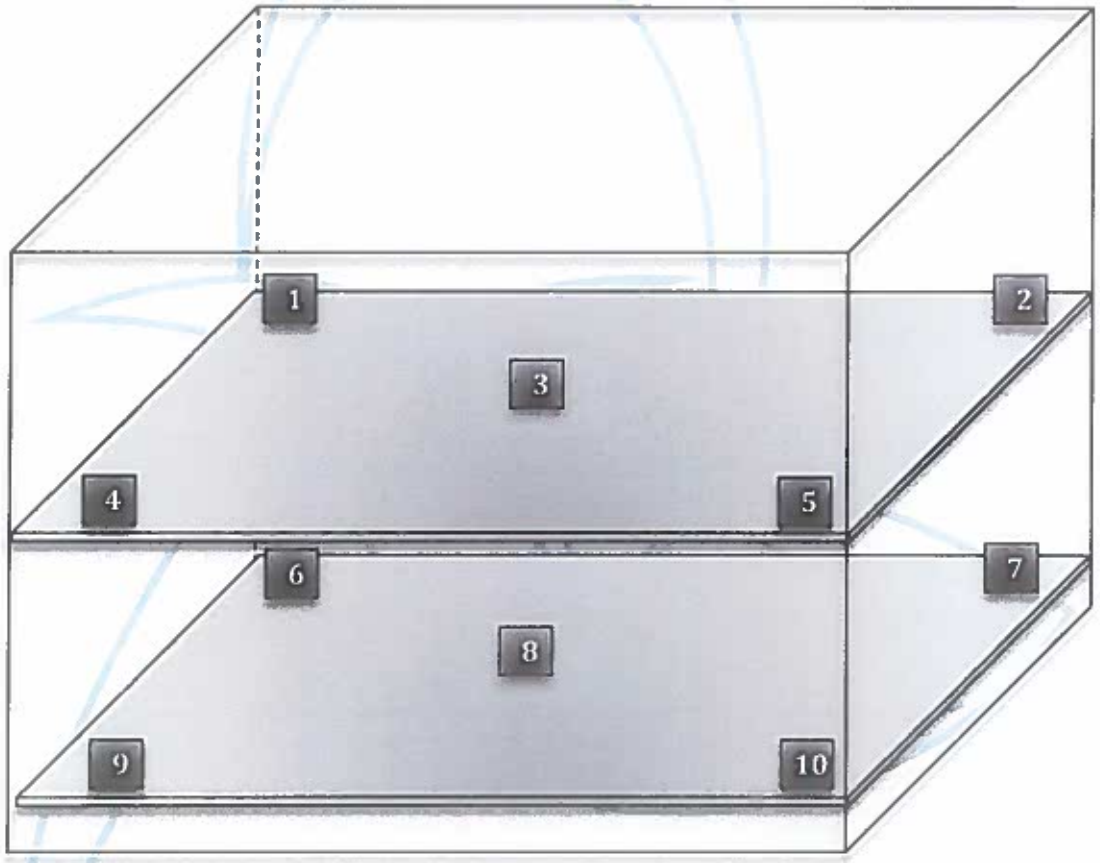
Methodology	
Pre-requisite	Steps 1 to 5 must be completed before the mapping protocol can finally be approved.
Step (1)	**Selecting Data Logger:** - The selected data loggers have been previously calibrated (on annual basis) at points covering the study range. For their specification, see point 2.3 in Annex 01.01 (PQ Results Data Sheets) and their calibration certificates are attached in the turn over package (Annex 01.02).
Step (2)	**Designating the Techncial Team:** - See point "5. SIGNATURE LOG" including the list of the team members with their signatures/initials for traceability.
Step (3)	**Determining the system under qualification specifications:** - Document volume, drawings, and heating/cooling component locations.
Step (4)	**Defining Acceptance Criteria:** - Base criteria on product/equipment requirements and/or according to the customer requirement (or omit for exploratory studies).
Step (5)	**Determination of EDLM Locations:** - As explained in point 3.3, we will need 10 EDLMS to perform accurate qualification for this Incubator.
Step (6)	**Recording EDLM and thermostat Locations:** - The exact location of each data logger in Incubator is specified in the layout, see point 3.7 in this protocol. - For the table of EDLM locations and the controller set point, see data sheet no. (01.01.01) in Annex 01.01 (PQ Results Data Sheets).
Step (7)	**Labelling and Programming EDLMs:** - Assign unique IDs and record serial numbers of each EDLM. - Program each EDLM with the same sampling interval which should be set between 1 and 15 minutes. Set the same start time for all units. - For the exact study design, see point 2.4 in Annex 01.01 (PQ Results Data Sheets).
Step (8)	**Fixing EDLMs in Position:** - Position and fasten the EDLMs so that they cannot be damaged or displaced during the course of routine operations. - Ensure that sufficient time is allowed for the EDLMs to be conditioned to the ambient temperature before the mapping exercise begins.
Step (9)	**Conducting Mapping Exercise:** - For the exact study design including study period details, see point 2.4 in Annex 01.01 (PQ Results Data Sheets)
Step (10)	**Performing Intervention Tests:** - Power Failure (Blackout): For the exact test design see point 2.3 in Annex 01.01 (PQ Results Data Sheets). - Door Opening: For the exact test design, see point 2.3 in Annex 01.01 (PQ Results Data Sheets).
Step (11)	**Data Analysis:** - Download the EDLM readings and consolidate the data for the study analysis. - Issue the report and identify the hottest point, coolest point attained and calculation of mean kinetic temperature. - Mark the area of hottest and coldest points. - Review the report and note down the maximum, minimum temperature reached during the interventions (power failure, door opening) and the time required to regain the temperature.

3.6 Study Design

Heat Distribution Study Design					
Controller Setting: @ °C (will be determined at the execution phase)					
Acceptance Criteria: (42 - 44) °C					
Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	Full Load (130 Plates, 8 Bottles & 25 Tubes)	dd/mm/yyyy hr:min AM/PM	dd/mm/yyyy hr:min AM/PM	1 Day (24 hrs.)	2 minutes

intervention Tests Study Design					
Test No.	Test Description	Start Date	Stop Date	Test Period	Sample Frequency
1.	Power Failure (Blackout)	dd/mm/yyyy hr:min AM/PM	dd/mm/yyyy hr:min AM/PM	30 minutes	2 minutes
2.	Door Opening	dd/mm/yyyy hr:min AM/PM	dd/mm/yyyy hr:min AM/PM	5 minutes	2 minutes

3.7 Endorsed Layout and Data Loggers' Distribution



3.8 Acceptance Criteria

The general acceptance criteria for PQ stage specify that the results of all the locations envisaged in this Protocol, when correctly run and documented in the attached forms, confirm the expected result.

3.9 Results Evaluation

After conducting the performance qualification study, the results will be thoroughly evaluated to assess temperature distribution, uniformity, and stability within the storage environment. Key aspects to consider in the final report after the evaluation include:

- Comparison of measured temperatures against set criteria and industry standards.
- Analysis of data trends and patterns to understand the overall thermal performance of the facility.
- Identification of temperature variations, and hot/cold spots would be identified for future monitoring.

3.10 Deviation Report

Any observed deviations from acceptance criteria encountered while running the performance qualification shall be recorded in the specific form named "Deviation Report" enclosed in (Data Sheet Number 01.01.03.01 in Annex 01.01 (PQ Results Data Sheets)) to be reported to UTOPIA PHARMACEUTICAL for taking and following up the corrective actions for those deviations.

3.11 Conclusion and Recommendations

- Based on the results of the performance qualification study, a conclusion will be drawn regarding the effectiveness of the temperature control system and the overall thermal stability of the system. The conclusion will summarize the key findings of the study and address whether the system meets the required temperature specifications for intended use.
- Following the evaluation and conclusion of the thermal mapping study, recommendations will be provided to improve temperature management and enhance the overall efficiency of the system. By incorporating the following recommendations, organizations can optimize temperature control, mitigate risks of product degradation, and ensure compliance with regulatory requirements. These recommendations may include:
  - Implementing adjustments to the temperature control system to address identified hot/cold spots.
  - Upgrading controlling systems to improve temperature stability.
  - Enhancing monitoring and alarm systems for better temperature control.
  - Establishing protocols for door opening/closing procedures to minimize temperature fluctuations.
  - Conducting regular maintenance and calibration of temperature monitoring devices.

3.12 Final Performance Qualification Report

After all the studies envisaged in this Performance Qualification Protocol, a Final Performance Qualification Report shall be issued. This Report consists of multiple sections.

In the first section, the results of all the studies run during Performance Qualification stage shall be recorded in the proper table.

The next section provides a table where deviations encountered, if any, shall be recorded, also specifying its description and the deviation closing date.

The last section consists of one page and shall attest revision and approval of all results obtained by appointed Officials.

When all tests are performed and deviations are closed, the Report will be finally approved by the appointed Officials.

3.13 Re-Validation and Management of Changes/Modifications

- Any major changes/modifications made to the system after its qualification shall be recorded in "Change Control" procedure of UTOPIA PHARMACEUTICAL.
- Each significant change or modification made to the system after this Protocol has been tested requires that the need to re-submit the system to another Re-Qualification procedure is evaluated. Reasons shall be given for not proceeding to a new Re-Qualification.

4. REFERENCES

(1) ISPE Good Practice Guide: Controlled Temperature Chambers – Commissioning and Qualification, Mapping and Monitoring (Second Edition), December 2021.

(2) WHO "Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products" Technical Supplement 7, May 2015.

(3) WHO "Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products" Technical Supplement 8, May 2015.

(4) Health Products Regulatory Authority (HPRA): Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances

(5) 21CFR 211.142 and 211.150: Storage and Distribution.

5. SIGNATURE LOG

Printed Name	Title	Company / Department	Initials	Signature
Mohamed Hassan	Technical Office Team Leader	TAG	M.H	M. Hass
Abdelrahman Ramadan	Site Engineer	TAG	A.R	A. Ramdan
Noha Essam	Technical Office Senior	TAG	N.S	Noha Essam
Ahmed Tarek	Technical Manager	TAG	A.T	