

Performance Qualification Report

For
Incubator
(EQ-QCM-026)

LIPTIS

6th of October City



Report Issue date : 14/04/2025

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1. Report Review and Approval

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Change History

No.	Version No.	Amended Page No.	Reason for change	Issued Date
1.	01	NA	NA	14/04/2025

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

2. Introduction

2.1 Glossary/Definitions

- 🔗 **Performance Qualification (PQ):** is the final step of qualifying equipment. In this phase, the qualification and validation team verify and document that the user requirements are verified as being met. It is the method of validating or qualifying equipment. The purpose is 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 equipment.
 - 🔗 **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.
 - 🔗 **TTSP:** 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.
 - 🔗 **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.
 - 🔗 **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 store.
 - 🔗 **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 Performance Qualification Report for the Incubator located at LIPTIS aims to validate and ensure the proper functioning of it. we aim to confirm that the equipment is suitable for its intended use, complies with regulatory requirements and to verify that the equipment consistently performs within specified parameters and meets the required standards for accurate testing and analysis.

2.3 Report Scope

The scope of this report intends to cover the thermal qualification procedure and the heat distribution results of Incubator (EQ-QCM-026) located at LIPTIS with the following description:

Description	Incubator
Manufacturing	Binder
Model	KT053
S.N.	20190000006576
Code	EQ-QCM-026
Acceptance Criteria	(55 ~ 60) °C
Location	Micro Lab
Load Description	Empty
Key Operating Parameters	Temperature

2.4 Report Purposes

- 🔗 To evaluate the heat distribution profiles and trends throughout the Incubator located at LIPTIS.
- 🔗 To ensure uniformity and compliance with regulatory standards and to verify that the Incubator meets regulatory requirements for temperature control.
- 🔗 To identify any areas with significant temperature variations, ensuring consistent conditions across the entire area.
- 🔗 To determine the hot and cold spots attained during thermal qualification of the specified Incubator to identify the locations where the monitoring sensors should preferentially be located.
- 🔗 The study helps in identifying potential risks associated with temperature differentials, hot/cold spots, or inadequate temperature control. By determining areas of concern, LIPTIS can proactively implement corrective measures to reduce risks of product degradation or loss.

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2.5 Roles and Responsibility

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

2.5.1 LIPTIS

- ✎ Responsible for the operational aspects of the equipment being qualified.
- ✎ Provides access to the equipment, coordinate and assist in addressing any equipment-related issues that may impact the mapping process.
- ✎ Develop the project timeline and oversee the entire thermal qualification project, including planning, coordination, and execution.
- ✎ 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.
- ✎ Determine the corrective actions and fill the deviation form if needed.
- ✎ Review the report for compliance after execution and ensure that the protocol aligns with regulatory requirements and company policies.
- ✎ Approve the report after qualification execution.

2.5.2 TAG

- ✎ Execute the qualification only after the protocol has been approved by LIPTIS.
- ✎ Develop the project timeline and oversee the entire thermal qualification project, including planning, coordination, and execution.
- ✎ Assign tasks to the responsible team members, ensure adherence to the approved protocol, and manages communication with stakeholders.
- ✎ Assure that each instrument used for qualification is calibrated before the use and meets the criteria of the guideline and its calibration certificate is attached to this report.
- ✎ Distribute temperature 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.
- ✎ Analyze and interpret the data collected during the thermal qualification study.
- ✎ Process raw data, identify temperature trends, generate reports, and communicate findings to LIPTIS for further action.
- ✎ Assure that data from tests and/or verifications, executed by TAG, are properly recorded in an acceptable format on work sheet and/or test documentation attached to this report.
- ✎ Store the raw data and compare test results with the acceptance criteria and determine if it conform or not conform.
- ✎ Manage the documentation associated with the thermal qualification project.
- ✎ 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.

3. 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.
- The reference equipment to be used for the heat distribution study will be calibrated data loggers with suitable computer equipment and software is needed to store and analyze the data.
- The description of the used EDLMs:

Used Reference Equipment Description						
Description	No. of EDLMs	Location	Accuracy	Manufacturer	Model	Calibration Due Date
Data Logger	10	Inside Incubator	± 0.5 °C	LOG TAG	HAXO-08	Dec., 2025
Note: The calibration certificates of each used data logger are attached with this report, see Annex No. (5).						

4. Locations and Rationale for Distributing Data Loggers

By distributing data loggers at various locations within the Incubator, we can ensure that temperature remains consistent throughout the unit, minimizing the risk of temperature differentials that could affect products integrity. 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. The exact location of data loggers in Incubator are specified in separate layout, see Annex No. (1).

- Top Shelf:** Placing a data logger on the top shelf enables monitoring of temperature variations at the highest point within the Incubator, 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 Incubator 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.
- Centre:** Placing a data logger in the center of the Incubator 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.

5. Procedure

- 5.1 The following steps outline the procedure for conducting the performance qualification study after the approval of the mapping protocol:
- 5.1.1 Ensure the Incubator is correctly installed and calibrated according to manufacturer specifications and verify that the equipment calibration is within acceptable limits and meets required standards.
 - 5.1.2 Since the volume of the Incubator is less than 2000 L, 10 data loggers needed to be distributed inside it.
 - 5.1.3 Each data logger marked with its serial number.
 - 5.1.4 The location each data logger in the Incubator shown in the layout attached with this report, see Annex No. (1).
 - 5.1.5 The mapping study was designed as follow:

Heat Distribution Study Design					
Controller Setting: @ 58 °C					
Acceptance Criteria: (55 ~ 60) °C					
Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	Empty	08/04/2025 09:00 PM	09/04/2025 09:00 PM	01 Day	02 minutes

- 5.1.6 Allow the Incubator to stabilize for a predetermined period to reach thermal equilibrium.
- 5.1.7 The interventions have been performed as follows:
 - 5.1.7.1 **Power Failure (Blackout) and Recovery Test:**
The power has been shut-down and following a 10-minutes period of the power being cut, it was subsequently turned on in order to commence the calculation of the recovery time as specified in Appendix No. (2).
 - 5.1.7.2 **Door Opening and Recovery Test:**
The door has been opened and following a 3-minutes period of the door being open, it was subsequently closed in order to commence the calculation of the recovery time as specified in Appendix No. (2).
- 5.1.8 Data loggers have been collected and the data have been downloaded from each data logger for analysis.
- 5.1.9 Observations and results of the heat distribution study have been recorded in the mapping data sheet, see Appendix No. (1 & 3).
- 5.1.10 The hot and cold spots have been identified for future monitoring and marked in the attached layout, see Appendix No. (3) and Annex No. (1).
- 5.1.11 Observations and results of the interventions have been recorded in the interventions data sheet, see Appendix No. (2 & 3).
- 5.1.12 The print outs of the heat distribution study have been taken and attached along with this report, see Annex No. (2).
- 5.1.13 The print outs of the intervention tests have been taken and attached along with this report, see Annex No. (3 & 4).

5.2 Mean Kinetic Temperature Calculations

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.

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

Where:

T_k = MKT in °K

ΔH = Heat of activation/activation energy

R = Universal gas constant ($8.3144 \times 10^{-3} \text{ kJ.Mole}^{-1} \cdot \text{°K}^{-1}$)

T = Temperature in °K

n = Total number of equal time periods over which data are collected

6. Acceptance Criteria

As per customer requirement, the temperature within Incubator have been recorded continuously for a period of 01 day as 1 cycle with recording interval of 02 minutes and the recorded temperature should be in this range (55 ~ 60) °C.

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7. Requalification Frequency

- 🔗 Thermal qualification will be repeated on annual basis as per LIPTIS qualification plan.
- 🔗 Requalification will be performed if any significant modification to the premises, changes in stock layout or maintenance have been occurred before the annually planned qualification.
- 🔗 The scheduled qualification will take place: next year.

8. Results Evaluation

- 🔗 The measured temperatures of each location inside the Incubator have been recorded and evaluated against the accepted criteria, see Appendix No. (1).
- 🔗 Conclusion and summary of the heat distribution study and the hot/cold spots have been recorded, see Appendix No. (3).

9. Deviation Report (if needed)

Any observed deviations during thermal qualification study and their impact on the study results will be recorded in the deviation report to be reported to LIPTIS for taking and following up the corrective actions for those deviations, see Appendix No. (4).

10. Conclusion and Recommendations

- 🔗 Based on the results of the thermal mapping study, a conclusion will be drawn regarding the effectiveness of the temperature control system and the overall thermal stability of the equipment. The conclusion will summarize the key findings of the study and address whether the equipment meets the required temperature specifications for intended use.
- 🔗 The final conclusion of the heat distribution study has been recorded, see Appendix No. (3).
- 🔗 The recommended worst points for future monitoring have been recorded, see Appendix No. (3).
- 🔗 The recommended period for power failure has been recorded, see Appendix No. (3).
- 🔗 The recommended period for routine door opening has been recorded, see Appendix No. (3).

11. Appendices and Annexes

- Appendix No. (1): Heat distribution study results.
- Appendix No. (2): Intervention test results.
- Appendix No. (3): Performance qualification conclusion and recommendation.
- Appendix No. (4): Deviation report (if needed).
- Appendix No. (5): Photos of mapped area.
- Appendix No. (6): Reference equipment List.
- Appendix No. (7): Signature Log.
- Appendix No. (8): Final Review and approval.

- Annex No. (1): Incubator layout and data loggers' distribution with marked hot/cold spots.
- Annex No. (2): Print outs of heat distribution study (raw data uploaded on CD).
- Annex No. (3): Print outs of power failure (blackout) test (raw data uploaded on CD).
- Annex No. (4): Print outs of door opening test (raw data uploaded on CD).
- Annex No. (5): Reference equipment calibration certificates.

12. References

- WHO "Annex 9: Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products" Technical Supplement 6, May 2015.
- WHO "Annex 9: Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products" Technical Supplement 7, May 2015.
- WHO "Annex 9: Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products" Technical Supplement 8, May 2015.
- ISPE Good Practice Guide – Controlled Temperature Chambers (2016).
- IEC 60068-3-5: Supporting documentation and guidance – Confirmation of the performance of temperature chambers (2018)
- Health Products Regulatory Authority (HPRA): Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances
- USP (659) Packaging and storage requirement.
- USP (32) General Notice and requirements: Applying to standards, tests, assays, and other specifications of the United States Pharmacopeia.
- 21CFR 211.142 and 211.150: Storage and Distribution.

APPENDIX No. (1): Performance Qualification Test Results

1. Heat Distribution Study Data Sheet for Incubator (EQ-QCM-026)						
Controller Setting: @ 58 °C				Acceptance Criteria: (55 ~ 60) °C		
Load Description: Empty				Study Period: 1 Day		
Stabilization Started at		08/04/2025 09:00 PM		Stabilization ended at		09/04/2025 09:00 PM
Sensor Position	Sensor S/N	Actual				Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum	Mean Kinetic	
		T (°C)	T (°C)	T (°C)	T (°C)	
1.	1010161108	57.5	57.5	57.5	57.5	Yes
2.	1010148403	57.8*	57.8	57.8	57.8	Yes
3.	1010185533	57.1**	57.2	57.0**	57.1	Yes
4.	1010161122	57.4	57.4	57.2	57.4	Yes
5.	1010148397	57.3	57.3	57.2	57.3	Yes
6.	1010150020	57.7	57.7	57.6	57.7	Yes
7.	1010069358	57.8*	57.9*	57.8	57.8	Yes
8.	1010148395	57.7	57.7	57.6	57.7	Yes
9.	1010069356	57.6	57.7	57.6	57.6	Yes
10.	1010185522	57.5	57.6	57.5	57.5	Yes
Average for Incubator		57.54				

*: Maximum Temperature.

** : Minimum Temperature.

	Reviewed By (TAG)	Reviewed By (LIPTIS)
Name	Ahmed Tarek	
Signature		
Date	14/04/2025	

APPENDIX No. (2): Intervention Test Results

1. Door Opening Time Data Sheet for Incubator (EQ-QCM-026)				
Door Opening Period: 03 min (as per customer requirement)				
Test Date	Door Opening Time	Door Closing Time	Excursion Time	Recovery Time
10/04/2025	10:23 AM	10:26 AM	10:24 AM	13 min
1 st location to go out of the accepted criteria		All Locations get out at the same time	Holdover Period	≈ 01 min
Last location to be within accepted criteria		10	Recovery Period	13 min

Sensor Position	Sensor S/N	Max. Temp. recorded during the door opening	Min. Temp. recorded during the door opening	Holdover Time (within range)	Recovery Time (return within specified range)
		(°C)	(°C)	(hr:min)	(hr:min)
1.	1010161108	57.5	52.5	from 10:23 to ≈ 10:24	at 10:33
2.	1010148403	57.5	51.9	from 10:23 to ≈ 10:24	at 10:33
3.	1010185533	57.1	48.7**	from 10:23 to ≈ 10:24	at 10:37
4.	1010161122	57.2	49.3	from 10:23 to ≈ 10:24	at 10:35
5.	1010148397	57.2	50.3	from 10:23 to ≈ 10:24	at 10:37
6.	1010150020	57.4	52.2	from 10:23 to ≈ 10:24	at 10:33
7.	1010069358	57.6	50.4	from 10:23 to ≈ 10:24	at 10:35
8.	1010148395	57.7*	51.5	from 10:23 to ≈ 10:24	at 10:35
9.	1010069356	57.6	49.7	from 10:23 to ≈ 10:24	at 10:37
10.	1010185522	57.4	49.2	from 10:23 to ≈ 10:24	at 10:39

*: Maximum Temperature.

** : Minimum Temperature.

Reviewed By (TAG)		Reviewed By (LIPTIS)	
Name	Ahmed Tarek		
Signature			
Date	14/04/2025		

2. Power Failure (Blackout) Time Data Sheet for Incubator (EQ-QCM-026)

Power Cut Period: 10 min (as per customer requirement)

Test Date	Power Cut Time	Power Turn On Time	Excursion Time
10/04/2025	12:11 AM	12:21 AM	DLs didn't get out of the acceptance criteria
Holdover Period		10 min	
Recovery Time / Recovery Period		Since DLs didn't get out of the acceptance criteria, Recovery time can't be estimated	

Sensor Position	Sensor S/N	Max. Temp. recorded during the power cut	Min. Temp. recorded during the power cut	Holdover Time (within range)	Recovery Time (return within specified range)
		(°C)	(°C)	(hr:min)	(hr:min)
1.	1010161108	57.5	56.7	DL didn't get out of the acceptance criteria	
2.	1010148403	57.8*	56.7	DL didn't get out of the acceptance criteria	
3.	1010185533	57.1	56.4**	DL didn't get out of the acceptance criteria	
4.	1010161122	57.3	56.4**	DL didn't get out of the acceptance criteria	
5.	1010148397	57.2	56.6	DL didn't get out of the acceptance criteria	
6.	1010150020	57.6	56.6	DL didn't get out of the acceptance criteria	
7.	1010069358	57.8*	56.8	DL didn't get out of the acceptance criteria	
8.	1010148395	57.7	56.6	DL didn't get out of the acceptance criteria	
9.	1010069356	57.6	56.5	DL didn't get out of the acceptance criteria	
10.	1010185522	57.5	56.6	DL didn't get out of the acceptance criteria	

*: Maximum Temperature.

** : Minimum Temperature.

Reviewed By (TAG)		Reviewed By (LIPTIS)	
Name	Ahmed Tarek		
Signature			
Date	14/04/2025		

APPENDIX No. (3): Performance Qualification Conclusion and Recommendation

- Using 10 data loggers, the performance of the Incubator (EQ-QCM-026) has been performed with Full load to ensure the uniformity of the heat distribution within the Incubator.
- The following table presents a summary of the monitored data all over the 01-day period. All obtained values are not rounded.

Measurements	Actual	Location	Sensor
Minimum recorded temperature	57.0 °C	3	1010185533
Maximum recorded temperature	57.9 °C	7	1010069358
Minimum Average recorded temperature	57.1 °C	3	1010185533
Maximum Average recorded temperature	57.8 °C	2 & 7	1010148403 & 1010069358
Average recorded temperature	57.54 °C		
No. of Data Loggers used for this study: 10 Data loggers			

- The temperature data collected throughout the study day indicates uniformity and consistent temperature distribution across all the space of the Incubator.
- Location (7) and (3) have been identified as the hot and cold spots, respectively. To ensure continuous monitoring of challenging temperature conditions, we recommend installing monitoring sensors at these locations within the Incubator.
- The following table represents the observations from the intervention tests by simulating the routine work conditions:

Measurements		Actual	Location	Sensor
Minimum recorded temperature during door opening		48.7 °C	3	1010185533
Maximum recorded temperature during door opening		57.7 °C	8	1010148395
Holdover Period for door opening	≈ 01 min	Recovery Period for power cut		13 min
Minimum recorded temperature during power cut		56.4 °C	3 & 4	1010185533 & 1010161122
Maximum recorded temperature during power cut		57.8 °C	2 & 7	11010148403 & 1010069358
Holdover Period for power cut	10 min			
Recovery Period for power cut	Since DLs didn't get out of accepted criteria, Recovery time can't be estimated			

- In summary, the performance qualification study has been successfully conducted, confirming the reliability, accuracy, and consistency of the heat distribution within the Incubator. The successful outcomes of this rigorous testing validate the commitment to quality and regulatory compliance that enhance the efficiency and effectiveness of routine operations without any challenging conditions that may affect the TTSPPs.

Reviewed By (TAG)		Reviewed By (LIPTIS)	
Name	Ahmed Tarek		
Signature			
Date	14/04/2025		

APPENDIX No. (4): Deviation Report

Test Report (N°. and Description):		Deviation N°.:	
Description:			
Signature TAG		Date:	
Signature LIPTIS		Date:	
Corrective Action:			
Person in charge to close the deviation LIPTIS			
Expected closure date			
Signature TAG		Date:	
Signature QA LIPTIS		Date:	
Corrective Action Results			
Signature LIPTIS		Date:	
Deviation successfully solved?		Yes ☐ No ☐	
Signature:		Date:	
Signature:		Date:	

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APPENDIX No. (5): Photos of the Incubator



APPENDIX No. (6): Reference Equipment List

Reference Equipment List				
Reference equipment description	Manufacturer	Tag or ID Number	Most recent calibration date	Calibration Due Date
Data Logger	LOG TAG	1010161108	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010148403	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010185533	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010161122	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010148397	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010150020	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010069358	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010148395	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010069356	Dec.,2024	Dec.,2025
Data Logger	LOG TAG	1010185522	Dec.,2024	Dec.,2025

	Reviewed By (TAG)	Reviewed By (LIPTIS)
Name	Ahmed Tarek	
Signature		
Date	14/04/2025	

APPENDIX No. (7): Signature Log

[illegible]

This document contains confidential material of the company to be used exclusively by LIPTIS, its associated companies and contract personnel.

APPENDIX No. (8): Final Review and Approval

The review of the performance qualification execution and the relevant raw data allow concluding that the study has been:

POSITIVE ☒ PASS WITH DEVIATION ☐ NEGATIVE ☐

NOTES:

Approved by

Ahmed Tarek	TAG		14/04/2025
Name	Company	Signature	Date

Approved by

Name	Company	Signature	Date

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**ANNEX No. (1): Incubator Layout and Data Loggers' Distribution
with Marked Hot/Cold Spots**

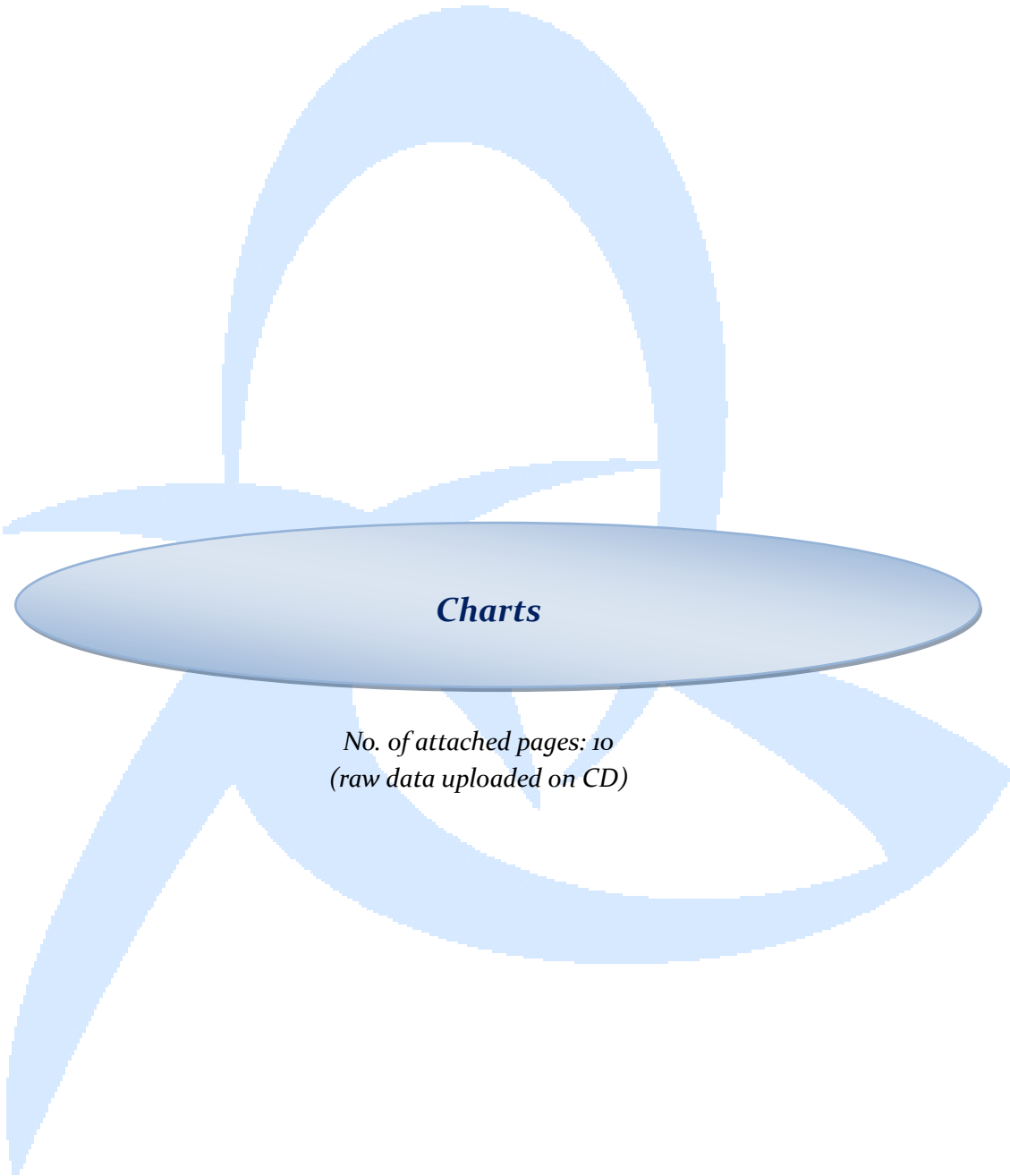


***Incubator Layout & Distribution of Data loggers
(with marked hot/cold spots)***

No. of attached pages: 01

	Performance Qualification Report <i>Incubator (EQ-QCM-026)</i>			
<i>Apr., 2025</i>	<i>Ver. No.: 01</i>	Doc. No.: PQR-T-07025	<i>F-7.4/09</i> Issue Date: 01/10/2024	<i>Page 22 of 25</i>

ANNEX No. (2): Print outs of Heat Distribution Study



	Performance Qualification Report <i>Incubator (EQ-QCM-026)</i>			
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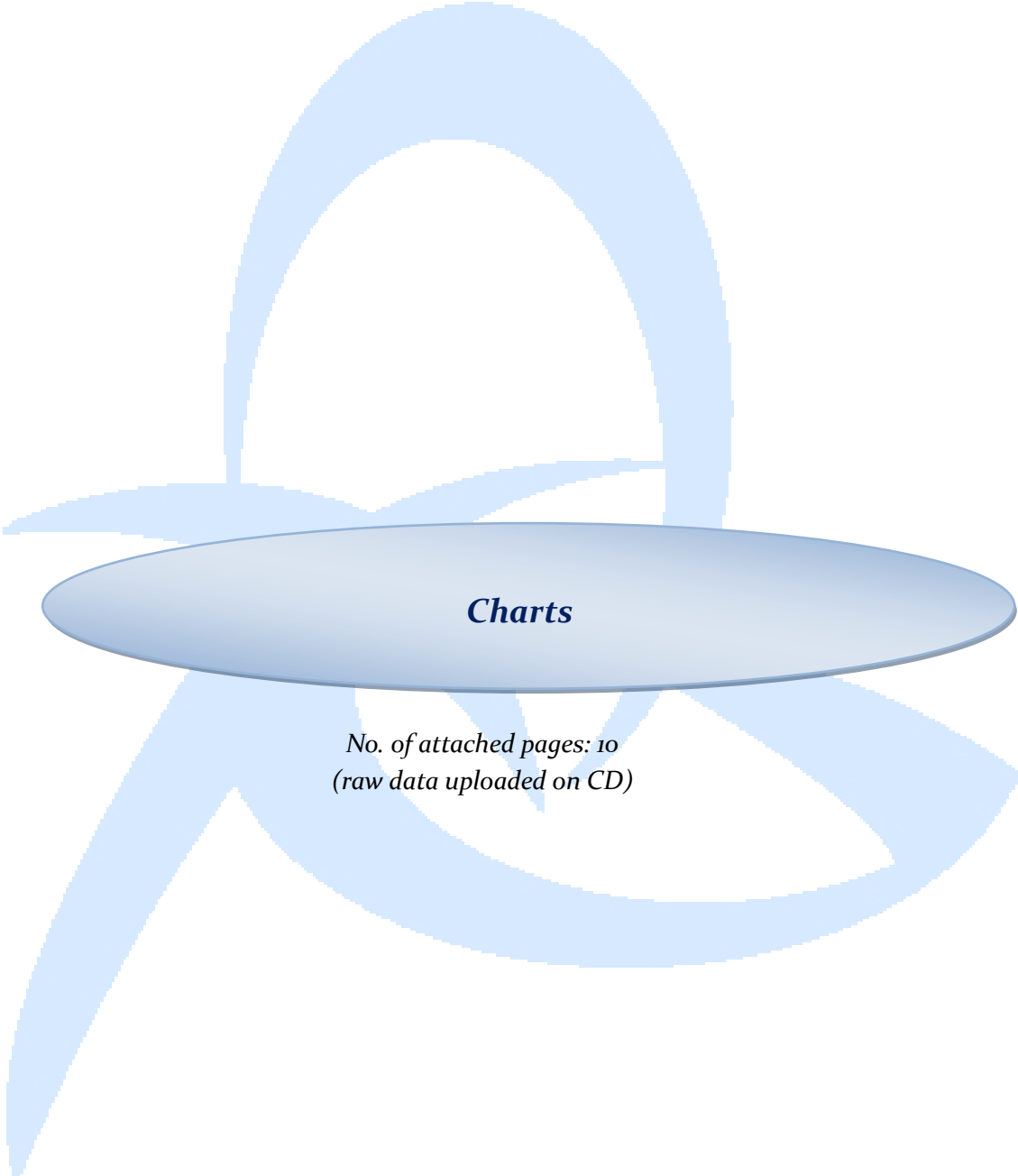
ANNEX No. (3): Door Opening Test

Charts

*No. of attached pages: 10
(raw data uploaded on CD)*

	Performance Qualification Report <i>Incubator (EQ-QCM-026)</i>			
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ANNEX No. (4): Power Failure (Blackout) Test



Charts

*No. of attached pages: 10
(raw data uploaded on CD)*

	Performance Qualification Report <i>Incubator (EQ-QCM-026)</i>			
<i>Apr., 2025</i>	<i>Ver. No.: 01</i>	Doc. No.: PQR-T-07025	<i>F-7.4/09</i> Issue Date: 01/10/2024	<i>Page 25 of 25</i>

ANNEX No. (5): Reference Equipment Calibration Certificates

