



VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

INCUBATOR

(QC-INC-04)

OF

UTOPIA PHARMACEUTICALS

10TH OF RAMADAN CITY

CLIENT:



QUALIFICATION PROVIDER:



Package Content:

VOL-01 Performance Qualification Protocol

Annex-01.01) Results Data Sheets

Annex-01.02) Turn Over Package (Attachments)



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1. REPORT REVIEW AND APPROVAL

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UTOPIA PHARMACEUTICALS Approver(s)

Name	Title	Company	Date	Signature

Change History

No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	10/06/2025

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



2. INTRODUCCION

2.1. Report Purpose

The purpose of this report is to document the results of the performance qualification study conducted to evaluate the temperature distribution within the Incubator located at **UTOPIA PHARMACEUTICALS**. The report includes the following points:

- 2.1.1 Detailed tables for the main cycle(s) conducted presenting the recorded:
 - ⌚ Average, maximum, and minimum recorded temperature for each location.
 - ⌚ Mean Kinetic Temperature (MKT) for each location.
 - ⌚ Average temperature across all locations.
- 2.1.2 Identifying the highest and lowest temperature points, and illustrating their locations on the layout diagram.
- 2.1.3 Providing a recommendation for the locations where the monitoring sensors should preferentially be located for future monitoring based on the determined hot and cold spots.
- 2.1.4 Identifying any excursions or abnormal variations observed during the study and providing a summary of those deviations in the deviation report along with any corrective action taken.
- 2.1.5 Identifying zones which should not be used for storage of TTSPPs or during routine use.
- 2.1.6 Detailed tables for the intervention tests conducted presenting:
 - ⌚ Excursion time and the first location got affected.
 - ⌚ Recovery time and the first location to gain its acceptable limits.
 - ⌚ Maximum and minimum recorded temperature for each location.
 - ⌚ The duration it took before any deviation occurred (Holdover Period).
 - ⌚ The time required for the temperature to return to acceptable limits (Recovery Period).



2.2. System Brief Description

The scope of this report intends to cover the performance qualification results of Incubator (QC-INC-04) located at UTOPIA PHARMACEUTICALS 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

2.3. Associated Material and Equipment Description

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	Oct., 2025



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2.4. Study Design

Heat Distribution Study Design

Controller Setting: @ 43 °C

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)	03/06/2025 06:00 AM	04/06/2025 06:00 AM	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)	04/06/2025 11:58 AM	04/06/2025 12:36 PM	30 minutes	2 minutes
2.	Door Opening	04/06/2025 01:50 PM	04/06/2025 02:04 PM	5 minutes	2 minutes



3. RESULTS DATA SHEETS

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ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01

MAIN CYCLE TEST RESULTS

Content:

01.01.01.01 Main Cycle No. (I) Test Results



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DATA SHEET 01.01.01.01

MAIN CYCLE NO. (I) TEST RESULTS



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Datasheet number 01.01.01.01.01: Main Cycle No. (1) Test Results Data Sheets

Heat Distribution Study Data Sheet for Incubator (QC-INC-04)						
Controller Setting: @ 43 °C			Acceptance Criteria: (42 - 44) °C			
Load Description: Full Load			Study Period: 1 Day (24 hrs.)			
Stabilization Started at		03/06/2025 06:00 AM		Stabilization ended at		04/06/2025 06:00 AM
Sensor Position	Sensor S/N	Actual			MKT. (°C)	Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum		
		Temp. (°C)	Temp. (°C)	Temp. (°C)		
1.	1010148421	43.1*	43.1	43.0	43.1	YES
2.	1010148409	43.0	43.1	43.0	43.0	YES
3.	1010157755	43.0	43.0	42.9	43.0	YES
4.	1010161099	42.9**	43.0	42.9	42.9	YES
5.	1010148418	42.9**	42.9	42.8**	42.9	YES
6.	1010150015	43.0	43.1	43.0	43.0	YES
7.	1010148406	43.0	43.0	42.9	43.0	YES
8.	1010069358	42.9**	42.9	42.8**	42.9	YES
9.	1010157537	43.0	43.0	42.9	43.0	YES
10.	1010149811	43.1*	43.2*	43.0	43.1	YES
Average for Incubator		43.0				

*: Maximum Temperature.

** : Minimum Temperature.

NOTES:

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

10/06/2025



Datasheet number 01.01.01.01.02: Main Cycle No. (1) Conclusion and Recommendation

- Using 10 data loggers, the performance of the Incubator (QC-INC-04) has been performed with full load to ensure the uniformity of the heat distribution within it.
- The following table presents a summary of the monitored data all over the 24-hours period. All obtained values are not rounded.

Results Summary			
Measurements	Actual	Location	Sensor
Minimum recorded temperature	42.8 °C	5 & 8	1010148418 & 1010069358
Maximum recorded temperature	43.2 °C	10	1010149811
Minimum Average recorded temperature	42.9 °C	4, 5, 8	1010161099, 1010148418 & 1010069358
Maximum Average recorded temperature	43.1 °C	1 & 10	1010148421 & 1010149811
Average recorded temperature	43.0 °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 (10) and (5 & 8) have been identified as the hot and cold spots for temperature, respectively.
- To ensure continuous monitoring of challenging temperature conditions, we recommend installing monitoring sensors at these locations (5, 8 & 10) within the Incubator .
- 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.
- All the registered charts, graphs, and raw data (CD) are attached in the TOP.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

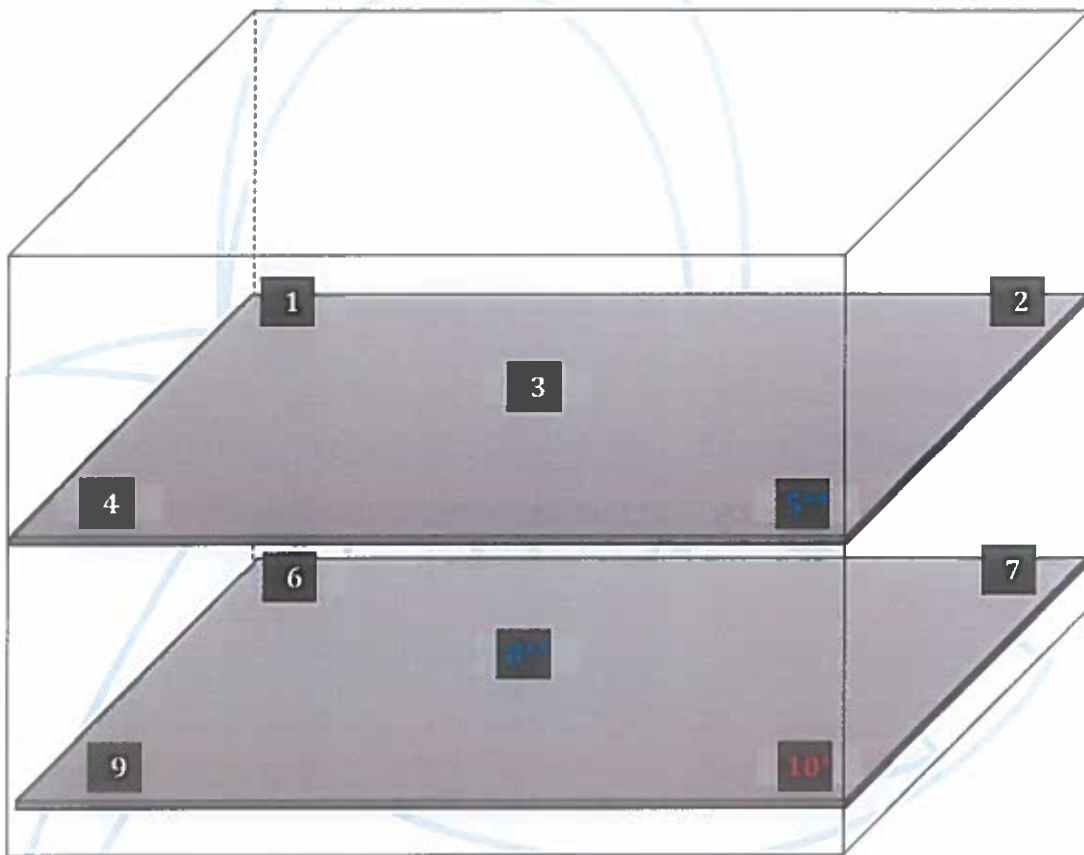
Ahmed Tarek

Date

10/06/2025



Datasheet number 01.01.01.01.03: Main Cycle No. (1) layout and data loggers' distribution with worst points



*: Hot Spot.
**: Cold Spot.



Datasheet number 01.01.01.01.04: Main Cycle No. (1) Qualification Photos



INCUBATOR PERFORMANCE QUALIFICATION

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RESULTS DATA SHEETS

DATA SHEET 01.01.02

INTERVENTION TEST RESULTS

Content:

01.01.02.01 Power Failure Test Results

01.01.02.02 Door Opening Test Results



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RESULTS DATA SHEETS

DATA SHEET 01.01.02.01

POWER FAILURE (BLACKOUT) TEST RESULTS



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Datasheet number 01.01.02.01.01: Power Failure Test Results Data Sheets

Power Failure (Blackout) Time Data Sheet for Incubator (QC-INC-04)				
Power Cut Period: 30 min (as per customer requirement)				
Acceptance Criteria: (42 - 44) °C				
Test Date	Power Cut Time	Power Turn on Time	Excursion Time	Recovery Time
04/06/2025	12:00 PM	12:30 PM	12:21 PM	12:37 PM
1 st location to go out of the accepted criteria		8	Holdover Period	21 min
Last location to be within accepted criteria		8	Recovery Period	7 min

Sensor Position	Sensor S/N	Actual recorded values during the power cut		Holdover Time (within range)	Recovery Time (return within specified range)
		Temperature			
		Max. Temp.	Min. Temp.		
		(°C)	(°C)		
1.	1010148421	43.1*	42.0	from 12:00 PM to 12:30 PM	No excursion occurred
2.	1010148409	43.0	41.9	from 12:00 PM to 12:30 PM	at 12:34 PM
3.	1010157755	43.0	42.1	from 12:00 PM to 12:30 PM	No excursion occurred
4.	1010161099	42.9	42.0	from 12:00 PM to 12:30 PM	No excursion occurred
5.	1010148418	42.9	41.8	from 12:00 PM to ~ 12:28 PM	at 12:36 PM
6.	1010150015	43.0	41.6	from 12:00 PM to 12:24 PM	at 12:36 PM
7.	1010148406	43.0	41.6	from 12:00 PM to 12:26 PM	at 12:36 PM
8.	1010069358	42.8	41.4**	from 12:00 PM to 12:21 PM	at 12:37 PM
9.	1010157537	43.0	41.5	from 12:00 PM to 12:22 PM	at 12:36 PM
10.	1010149811	43.1*	41.5	from 12:00 PM to 12:22 PM	at 12:36 PM

*: Maximum Temperature.

** : Minimum Temperature.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

10/06/2025



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Datasheet number 01.01.02.01.02: Power Failure Conclusion and Recommendation

- The following table presents the observations from the power failure test by simulating the routine work conditions. All obtained values are not rounded.

Results Summary			
Measurements	Actual	Location	Sensor
Minimum recorded temperature	41.4 °C	8	1010069358
Maximum recorded temperature	43.1 °C	10	1010149811
Holdover Period for Power Cut	21 min		
Recovery Period for Power Cut	7 min		

- All the registered charts, graphs, and raw data (CD) are attached in the TOP.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

10/06/2025



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DATA SHEET 01.01.02.02

DOOR OPENING TEST RESULTS



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Datasheet number 01.01.02.02.01: Door Opening Test Results Data Sheets

Door Opening Time Data Sheet for Incubator (QC-INC-04)				
Door Opening Period: 5 min (as per customer requirement)				
Acceptance Criteria: (42 - 44) °C				
Test Date	Door Opening Time	Door Closing Time	Excursion Time	Recovery Time
04/06/2025	01:51 PM	01:56 PM	01:52 PM	02:04 PM
1 st location to go out of the accepted criteria		All locations except no. (2 & 7)	Holdover Period	~ 1 min
Last location to be within accepted criteria		3, 4 & 7	Recovery Period	8 min

Sensor Position	Sensor S/N	Actual recorded values during the door opening		Holdover Time (within range)	Recovery Time (return within specified range)
		Temperature			
		Max. Temp.	Min. Temp.		
		(°C)	(°C)		
1.	1010148421	43.1*	40.6	from 01:51 PM to 01:52 PM	at 02:02 PM
2.	1010148409	43.0	41.3	from 01:51 PM to 01:54 PM	at 02:00 PM
3.	1010157755	43.0	41.0	from 01:51 PM to 01:52 PM	at 02:04 PM
4.	1010161099	42.9	39.6**	from 01:51 PM to 01:52 PM	at 02:04 PM
5.	1010148418	42.9	41.3	from 01:51 PM to 01:52 PM	at 02:02 PM
6.	1010150015	43.0	40.4	from 01:51 PM to 01:52 PM	at 02:02 PM
7.	1010148406	43.0	41.7	from 01:51 PM to 01:54 PM	at 02:04 PM
8.	1010069358	42.9	40.6	from 01:51 PM to ~ 01:52 PM	at 02:03 PM
9.	1010157537	43.0	39.8	from 01:51 PM to 01:52 PM	at 02:02 PM
10.	1010149811	43.1*	40.3	from 01:51 PM to 01:52 PM	at 02:02 PM

*: Maximum Temperature.

** : Minimum Temperature.

Reviewed By (TAG)

Reviewed By (UTOPHA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

[Signature]

Date

10/06/2025



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Datasheet number 01.01.02.02.02: Door Opening Conclusion and Recommendation

- The following table presents the observations from the door opening test by simulating the routine work conditions. All obtained values are not rounded.

Results Summary			
Measurements	Actual	Location	Sensor
Minimum recorded temperature	43.1 °C	1 & 10	1010148421 & 1010149811
Maximum recorded temperature	39.6 °C	4	1010161099
Holdover Period for Door Opening	~ 1 min		
Recovery Period for Door Opening	8 min		

- All the registered charts, graphs, and raw data (CD) are attached in the TOP.



Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

10/06/2025

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ANNEX 01.01
RESULTS DATA SHEETS

DATA SHEET 01.01.03
DEVIATION REPORT



Datasheet Number 01.01.03.01: Deviation Report

DEVIATION REPORT		Copy 01 of 01
Test Report (N°. and Description):		Deviation N°.:
Description:		
Signature TAG:		Date:
Signature UTOPIA PHARMACEUTICALS:		Date:
Corrective Action:		
Person in charge to close the deviation		Expected closure date:
Signature TAG:		Date:
Signature QA UTOPIA PHARMACEUTICALS:		Date:
Corrective Action results		
Signature UTOPIA PHARMACEUTICALS:		Date:
Deviation successfully solved? YES _____		NO _____
Signature:		Date:
Signature:		Date:



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ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.04

EQUIPMENT CALIBRATION VERIFICATION



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Datasheet Number 01.01.04.01: Reference Instruments Calibration Verification

Reference Instruments List					
Instrument Description				CALIBRATION	
No.	Instrument Description	Manufacturer/ Model	S.N.	Most recent calibration date	Calibration Due Date
1.	Data Logger	LOG TAG /HAXO-08	1010148421	Apr., 2025	Oct., 2025
2.	Data Logger	LOG TAG /HAXO-08	1010148409	Apr., 2025	Oct., 2025
3.	Data Logger	LOG TAG /HAXO-08	1010157755	Apr., 2025	Oct., 2025
4.	Data Logger	LOG TAG /HAXO-08	1010161099	Apr., 2025	Oct., 2025
5.	Data Logger	LOG TAG /HAXO-08	1010148418	Apr., 2025	Oct., 2025
6.	Data Logger	LOG TAG /HAXO-08	1010150015	Apr., 2025	Oct., 2025
7.	Data Logger	LOG TAG /HAXO-08	1010148406	Apr., 2025	Oct., 2025
8.	Data Logger	LOG TAG /HAXO-08	1010069358	Apr., 2025	Oct., 2025
9.	Data Logger	LOG TAG /HAXO-08	1010157537	Apr., 2025	Oct., 2025
10.	Data Logger	LOG TAG /HAXO-08	1010149811	Apr., 2025	Oct., 2025

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

10/06/2025



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ANNEX 01.01
RESULTS DATA SHEETS

DATA SHEET 01.01.05
LIST OF ATTACHEMENTS



Datasheet Number 01.01.05.01: List of Attachments

List of Attachments		
Attachment No.	Description	Location
01.02.01.01	Main Cycle No. (1) Printouts	Annex-01.02 (Turn Over Package)
01.02.01.02	Power Failure Printouts	Annex-01.02 (Turn Over Package)
01.02.01.03	Door Opening Printouts	Annex-01.02 (Turn Over Package)
01.02.01.04	Raw Data (on CD)	Annex-01.02 (Turn Over Package)
01.02.01.05	Inspection Label	Annex-01.02 (Turn Over Package)
01.02.01.06	Reference Equipment Calibration Certificates	Annex-01.02 (Turn Over Package)
01.02.01.07	Inspection Certificate	Annex-01.02 (Turn Over Package)

INCUBATOR PERFORMANCE QUALIFICATION

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

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Date

10/06/2025



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FINAL REVIEW AND APPROVAL

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

Comply ☒

Comply with Deviation ☐

Doesn't Comply ☐

NOTES:

Approved by	<u>Mohamed Hassan</u> Name	<u>M. Hassan</u> Signature	<u>T.O.T.L.</u> Title	<u>TAG</u> Company	<u>10/06/2025</u> Date
Approved by	<u>Abdelrahman Ramadan</u> Name	<u>A. Ramadan</u> Signature	<u>P.E.</u> Title	<u>TAG</u> Company	<u>10/06/2025</u> Date
Approved by	<u>Noha Essam</u> Name	<u>Noha Essam</u> Signature	<u>SR. T.O.E</u> Title	<u>TAG</u> Company	<u>10/06/2025</u> Date
Approved by	<u>Ahmed Tarek</u> Name	<u>Ahmed Tarek</u> Signature	<u>T.M.</u> Title	<u>TAG</u> Company	<u>10/06/2025</u> Date
Approved by	 Name	 Signature	 Title	 Company	 Date
Approved by	 Name	 Signature	 Title	 Company	 Date
Approved by	 Name	 Signature	 Title	 Company	 Date
Approved by	 Name	 Signature	 Title	 Company	 Date

