



VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR
INCUBATOR
(QC-INC-01)
OF
UTOPIA PHARMACEUTICAL
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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INCUBATOR PERFORMANCE QUALIFICATION

 UTOPIA THE LIFE YOU DESERVE		Vol 01) Annex 01.01) Results Data Sheets Incubator (QC-INC-01)		 TAG TECHNICAL AIR GATE
Feb., 2025	Rev. No.: 00	Doc. No.: PQR-M-00125	F-7.4/32 Issue Date: 02/02/2025	Page 3 of 26

1. REPORT REVIEW AND APPROVAL

TAG Author(s)

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Name	Title	Company	Date	Signature
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Name	Title	Company	Date	Signature
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UTOPIA PHARMACEUTICAL Reviewer(s)

Name	Title	Company	Date	Signature

UTOPIA PHARMACEUTICAL Approver(s)

Name	Title	Company	Date	Signature

Change History				
No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	16/2/2025

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 PHARMACEUTICAL. 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 TTSPs 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.
- Holdover time and recovery time 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-01) located at UTOPIA PHARMACEUTICAL with the following description:

System Brief Description	
Description	Incubator
Dimensions/Volume	55 Liters
Manufacturing	MEMMERT GmbH + Co.KG Germany
Model	IF55PLUS
S.N.	D221.1153
Code	QC-INC-01
Acceptance Criteria	(55 - 60) °C
Location	Incubation Room (MB-012)
Load Description	15 Bottles each shelf contains on BI
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	10 Dec., 2025



INCUBATOR PERFORMANCE QUALIFICATION

2.4. Study Design

Heat Distribution Study Design

Controller Setting: 57 °C

Acceptance Criteria: (55 ~ 60) °C

Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	15 Bottles each shelf contains on BI	06/02/2025 06:00 PM	07/02/2025 06:00 PM	1 days	2 minutes

intervention Tests Study Design

Test No.	Test Description	Start Date	Stop Date	Test Period	Sample Frequency
1.	Power Failure (Blackout)	13/02/2025 12:44 AM	13/02/2025 01:14 PM	30 minutes	2 minutes
2.	Door Opening	13/02/2025 02:00 PM	13/02/2025 02:05 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. (1) Test Results



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DATA SHEET 01.01.01.01

MAIN CYCLE NO. (1) 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-01)						
Controller Setting: 57 °C			Acceptance Criteria: (55 ~ 60) °C			
Load Description: 15 Bottles each shelf contains on BI			Study Period: 1 day			
Stabilization Started at		06/02/2025 06:00 PM		Stabilization ended at		07/02/2025 06:00 PM
Sensor Position	Sensor S/N	Actual			MKT. (°C)	Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum		
		Temp. (°C)	T (°C)	T (°C)		
1.	1010149813	57.2	57.3	57.0	57.2	YES
2.	1010161098	57.2	57.3	57.0	57.2	YES
3.	1010150020	57.1**	57.2	56.8**	57.1	YES
4.	1010082209	57.1**	57.2	56.8**	57.1	YES
5.	1010149993	57.2	57.3	56.9	57.2	YES
6.	1010069365	57.6	57.7	57.4	57.6	YES
7.	1010144276	57.2	57.2	57.0	57.2	YES
8.	1010148435	57.7*	57.8*	57.5	57.7	YES
9.	1010148436	57.7*	57.8*	57.5	57.7	YES
10.	1010148434	57.5	57.6	57.1	57.5	YES
Average for Incubator		57.35				

*: Maximum Temperature.

**: Minimum Temperature.

NOTES:

- 2 The worst values of temperature were determined based on the maximum and minimum of the average values, taking into account the highest and lowest recorded values during the study period.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICAL)

Name

Ahmed Tarek

Signature

Date

16-02-2025



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-01) has been performed with loaded to ensure the uniformity of the heat distribution within it.
- The following table presents a summary of the monitored data all over the 1-day period. All obtained values are not rounded.

Results Summary			
Measurements	Actual	Location	Sensor
Minimum recorded temperature	56.8 °C	3 & 4	1010150020 & 1010082209
Maximum recorded temperature	57.8 °C	8 & 9	1010148435 & 1010148436
Minimum Average recorded temperature	57.1 °C	3 & 4	1010150020 & 1010082209
Maximum Average recorded temperature	57.7 °C	8 & 9	1010148435 & 1010148436
Average recorded temperature	57.35 °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 (8 & 9) and (3 & 4) 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 (3, 4, 8 & 9) 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 TTSPs.
- All the registered charts, graphs, and raw data (CD) are attached in the TOP.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICAL)

Name

Ahmed Tarek

Signature

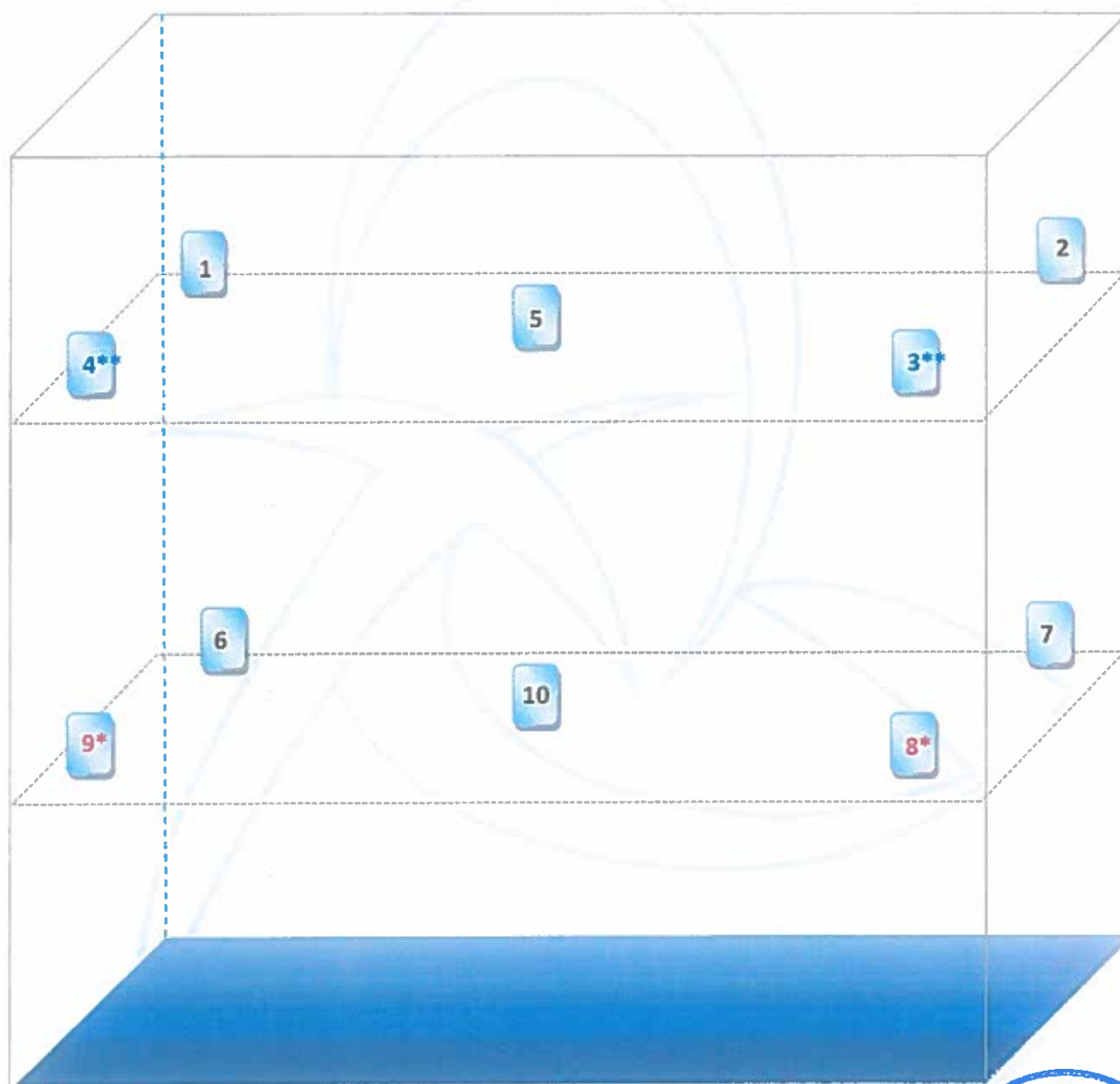


Date

16-02-2025



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



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



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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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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-01)				
Power Cut Period: 30 min (as per customer requirement)				
Acceptance Criteria: (55 ~ 60) °C				
Test Date	Power Cut Time	Power Turn on Time	Excursion Time	Recovery Time
11/02/2025	12:44 AM	01:14 PM	01:06 PM	01:28 PM
1 st location to go out of the accepted criteria		6th Location (1010069365) & 9th Location (1010148436)	Holdover Period	22 min
Last location to be within accepted criteria		All locations expect 1010148436, 1010069365 & 1010148435	Recovery Period	14 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.		
		Temp (°C)	T (°C)		
1.	1010149813	57.3	53.6	from 12:44 to 01:12	at 01:28
2.	1010161098	57.2	53.8	from 12:44 to 01:12	at 01:28
3.	1010150020	57.2	53.6	from 12:44 to 01:10	at 01:28
4.	1010082209	57.1	53.5	from 12:44 to 01:08	at 01:28
5.	1010149993	57.2	53.9	from 12:44 to 01:12	at 01:28
6.	1010069365	57.6	53.1**	from 12:44 to 01:06	at 01:26
7.	1010144276	57.2	53.3	from 12:44 to 01:10	at 01:28
8.	1010148435	57.7	53.4	from 12:44 to 01:08	at 01:26
9.	1010148436	57.8*	53.1**	from 12:44 to 01:06	at 01:24
10.	1010148434	57.6	54.2	from 12:44 to 01:14	at 01:28

*: Maximum Temperature.

** : Minimum Temperature.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICAL)

Name

Ahmed Tarek

Signature

[Signature]

Date

16-02-2025



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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	53.1 °C	6 & 9	1010069365 & 1010148436
Maximum recorded temperature	57.8 °C	9	1010148436
Holdover Period for Power Cut	22 min		
Recovery Period for Power Cut	14 min		

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

Reviewed By (TAG)		Reviewed By (UTOPIA PHARMACEUTICAL)	
Name	Ahmed Tarek		
Signature			
Date	16-02-2025		



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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-01)				
Door Opening Period: 5 min (as per customer requirement)				
Acceptance Criteria: (55 ~ 60) °C				
Test Date	Door Opening Time	Door Closing Time	Excursion Time	Recovery Time
11/02/2025	02:00 PM	02:05 PM	02:02 PM	02:14 PM
1 st location to go out of the accepted criteria		All Locations were going out at the same time.	Holdover Period	2 min
Last location to be within accepted criteria		5th Location (1010149993)	Recovery Period	10 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.		
		Temp. (°C)	T (°C)	(hr:min)	(hr:min)
1.	1010149813	56.7	50.3	from 2:00 to 2:02	at 2:10 PM
2.	1010161098	56.9	50.4	from 2:00 to 2:02	at 2:12 PM
3.	1010150020	57.5	49.7	from 2:00 to 2:02	at 2:12 PM
4.	1010082209	57.5	50.5	from 2:00 to 2:02	at 2:10 PM
5.	1010149993	57.5	50.3	from 2:00 to 2:02	at 2:14 PM
6.	1010069365	57.1	51.5	from 2:00 to 2:02	at 2:10 PM
7.	1010144276	56.8	50.9	from 2:00 to 2:02	at 2:12 PM
8.	1010148435	56.5	48.8**	from 2:00 to 2:02	at 2:10 PM
9.	1010148436	58.1*	52.1	from 2:00 to 2:02	at 2:08 PM
10.	1010148434	56.8	51.5	from 2:00 to 2:02	at 2:12 PM

*: Maximum Temperature.

**: Minimum Temperature.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICAL)

Name

Ahmed Tarek

Signature



Date

16-02-2025



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	48.8 °C	8	1010148435
Maximum recorded temperature	58.1 °C	9	1010148436
Holdover Period for Door Opening	2 min		
Recovery Period for Door Opening	10 min		

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

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICAL)

Name Ahmed Tarek
 Signature 
 Date 16-02-2025



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ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.03

DEVIATION REPORT



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Datasheet Number 01.01.03.01: Deviation Report**DEVIATION REPORT**

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Test Report (N°. and Description):

Deviation N°.:

Description:

Signature **TAG:**

Date:

Signature **UTOPIA PHARMACEUTICAL:**

Date:

Corrective Action:

Person in charge to close the deviation

Expected closure date:

Signature **TAG:**

Date:

Signature QA **UTOPIA PHARMACEUTICAL:**

Date:

Corrective Action results

Signature **UTOPIA PHARMACEUTICAL:**

Date:

Deviation successfully solved? YES _____

NO _____

Signature:

Date:

Signature:

Date:



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DATA SHEET 01.01.04

EQUIPMENT CALIBRATION VERIFICATION



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DATA SHEET 01.01.05

LIST OF ATTACHEMENTS



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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)

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICAL)

Name

Ahmed Tarek

Signature

[Signature]

Date

16-02-2025



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	Salma Salah	<i>Salma Salah</i>	T.O.E	TAG	16.02.2025
	Name	Signature	Title	Company	Date
Approved by	Ahmed Mohamed	<i>Ahmed</i>	S.E.	TAG	16.02.2025
	Name	Signature	Title	Company	Date
Approved by	Noha Essam	<i>Noha Essam</i>	SR. T.O.E	TAG	16.02.2025
	Name	Signature	Title	Company	Date
Approved by	Ahmed Tarek	<i>Ahmed</i>	T.M.	TAG	16.02.2025
	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
Approved by					
	Name	Signature	Title	Company	Date

