To verify that this document is original, please check this QR code

VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

REFRIGERATOR

(QC-REF-06)

OF

UTOPIA PHARMACEUTICALS

10TH OF RAMADAN CITY

CLIENT: UTOPIA THE LIFE YOU DESERVE

QUALIFICATION PROVIDER: TAG TECHNO AIR GATE

Package Content:

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

EGYPT: 26 Al Israa St., Lebanon Sq., Mohandseen, Giza, Egypt
KSA: 3321, Prince Mamdouh Bin Abdulaziz St., Al Sulaymaniyah, Riyadh. KSA
UAE: Sharjah Media City, Sharjah, UAE
www.technoairgate.com info@technoairgate.com
+201023310801
+966543728852
+971502013049
+20233034440

Table of Content

CALIBRATION TAG TECHNO AIR GATE

1. REPORT REVIEW AND APPROVAL

TAG Author(s)

Name	Title	Company	Date	Signature
Mohamed Hassan	T.O.T.L.	TAG	11/06/2025	M. Hass

TAG Inspector(s)

Name	Title	Company	Date	Signature
Abdelrahman Ramadan	P.E.	TAG	11/06/2025	A. Ramdan

TAG Reviewers(s)

Name	Title	Company	Date	Signature
Noha Essam	SR. T.O.E	TAG	11/06/2025	Noha Essam

TAG Approver(s)

Name	Title	Company	Date	Signature
Ahmed Tarek	T.M.	TAG	11/06/2025	

UTOPIA PHARMACEUTICALS Reviewer(s)

Name	Title	Company	Date	Signature

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	11/06/2025

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

CALIBRATION TAG TECHNO AIR GATE

2. INTRODUCION

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 Refrigerator 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 Refrigerator (QC-REF-06) located at UTOPIA PHARMACEUTICALS with the following description:

System Brief Description	
Description	Refrigerator (with Freezer)
Dimensions/Volume	350 Liters for Refrigerator 350 Liters for Freezer
Manufacturing	DESMON
Model	DS-GMB7B/ITS-C
S.N.	22POP 002086
Code	QC-REF-06
Acceptance Criteria	(2 - 8) °C for Refrigerator ((-25) to (-10)) °C for Freezer
Location	Retained Sample Room (LB-025)
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	20	Inside Refrigerator & Freezer	± 0.5 °C	LOG TAG	HAXO-08	Oct., 2025

2.4. Study Design

Heat Distribution Study Design					
Controller Setting: @ 4.5 °C for Refrigerator and @ -20 °C for Freezer					
Acceptance Criteria: (2 - 8) °C for Refrigerator and ((-25) to (-10)) °C for Freezer					
Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	Full Load The refrigerator consists of two shelves: 1st Shelf: includes 7 bottles (80 mL) & 7 bottles (135 mL) . 2nd Shelf: Empty (not used in storage process and replaced with the bottom part). Bottom Part: includes 15 bottles (80 mL), 7 bottles (30 mL) & 6 bottles (135 mL). The freezer consists of two racks and each rack includes 50 bottles (125 mL).	02/06/2025 07:00 PM	03/06/2025 07:00 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)	04/06/2025 11:10 AM	04/06/2025 11:50 AM	40 minutes	2 minutes
2.	Door Opening	04/06/2025 01:28 PM	04/06/2025 01:33 PM	5 minutes	2 minutes

CALIBRATION TAG TECHNO AIR GATE

3. RESULTS DATA SHEETS

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.01

MAIN CYCLE TEST RESULTS

Content:

CALIBRATION TAG TECHNO AIR GATE

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.01.01

MAIN CYCLE NO. (1) TEST RESULTS

CALIBRATION TAG TECHNO AIR GATE

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

Heat Distribution Study Data Sheet for Refrigerator (QC-REF-06)

Refrigerator	Freezer
Controller Setting: @ 4.5 °C for Refrigerator. **Acceptance Criteria:** (2 - 8) °C for Refrigerator.	**Controller Setting:** @ -20 °C for Freezer **Acceptance Criteria:** ((-25) to (-10)) °C for Freezer
Load Description (Both): Full Load	**Study Period (Both):** 1 Day (24 hrs.)
Stabilization Started at (Both) 02/06/2025 07:00 PM	**Stabilization ended at (Both)** 03/06/2025 07:00 PM

Sensor Position	Sensor S/N	Actual			MKT. (°C)	Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum		
		Temp. (°C)	Temp. (°C)	Temp. (°C)		
Refrigerator Part						
1.	1010149815	3.9	4.9	3.3	3.9	YES
2.	1010161122	4.2	5.2	3.7	4.2	YES
3.	1010161121	4.3	5.3	3.7	4.3	YES
4.	1010157523	4.9	5.7	4.3	4.9	YES
5.	1010148394	5.1*	6.0*	4.5	5.1	YES
6.	1010157516	2.1	2.5	1.7	2.1	NO
7.	1010157521	1.8**	2.3	1.5**	1.8	NO
8.	1010157751	1.9	2.4	1.7	1.9	NO
9.	1010157511	3.4	3.7	3.2	3.4	YES
10.	1010150014	3.1	3.4	2.9	3.1	YES
Average for Refrigerator		3.5				
Freezer Part						
11.	1010161113	-16.9**	-10.8	-18.4**	-16.8	YES
12.	1010144277	-16.8	-10.7	-18.1	-16.7	YES
13.	1010150017	-16.3	-10.5	-17.4	-16.1	YES
14.	1010149991	-16.2	-10.6	-17.3	-16.1	YES
15.	1010161102	-15.9	-10.3*	-17.1	-15.8	YES
16.	1010149999	-16.5	-11.2	-17.7	-16.4	YES
17.	1010148434	-16.6	-10.9	-17.8	-16.5	YES

18.	1010150000	-16.7	-11.2	-17.9	-16.6	YES
19.	1010157517	-16.3	-11.0	-17.3	-16.2	YES
20.	1010150019	-15.2*	-10.3*	-16.4	-15.1	YES
Average for Freezer		-16.3				

*: Maximum Temperature.
**: Minimum Temperature.

NOTES:

Locations No. (6, 7 and 8) exhibited deviations from the specified temperature threshold (2 - 8) °C for during the 24-hours sampling period.

As per customer requirement, since USP 35 (10.30.40. Controlled Cold Temperature) stated that:
"" Controlled cold temperature" is defined as temperature maintained thermostatically between 2° and 8° (36° and 46° F), that allows for excursions in temperature between 0° and 15° (32° and 59° F) that may be experienced during storage, shipping, and distribution such that the allowable calculated mean kinetic temperature is not more than 8° (46° F). Transient spikes up to 25° (77° F) may be permitted if the manufacturer so instructs and provided that such spikes do not exceed 24 hours unless supported by stability data or the manufacturer instructs otherwise."

And since, MKT calculated value of location no. (6) has remained within the defined acceptable limits, this location is not classified as non-compliant but to ensure continued compliance and thermal stability, we recommend installing monitoring sensor at this location for continuous assessment of heat distribution during the routine work.

And since the MKT calculated values of locations no. (7 and 8) have deviated from the defined acceptable limits, these locations are classified as non-compliant and they should be neglected in the future storage processes.

	Reviewed By (TAG)	Reviewed By (UTOPIA PHARMACEUTICALS)
Name	Ahmed Farek	
Signature		
Date	11/06/2025	

CALIBRATION TAG TECHNO AIR GATE

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

- Using 20 data loggers, the performance of the Refrigerator (QC-REF-06) 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**
Refrigerator Part			
Minimum recorded temperature	1.5 °C	7	1010157521
Maximum recorded temperature	6.0 °C	5	1010148394
Minimum Average recorded temperature	1.8 °C	7	1010157521
Maximum Average recorded temperature	5.1 °C	5	1010148394
Average recorded temperature	3.5 °C		
Freezer Part			
Minimum recorded temperature	-18.4 °C	11	1010161113
Maximum recorded temperature	-10.3 °C	15 & 20	1010161102 & 1010150019
Minimum Average recorded temperature	-16.9 °C	11	1010161113
Maximum Average recorded temperature	-15.2 °C	20	1010150019
Average recorded temperature	-16.3 °C		
No. of Data Loggers used for this study: 20 Data loggers			

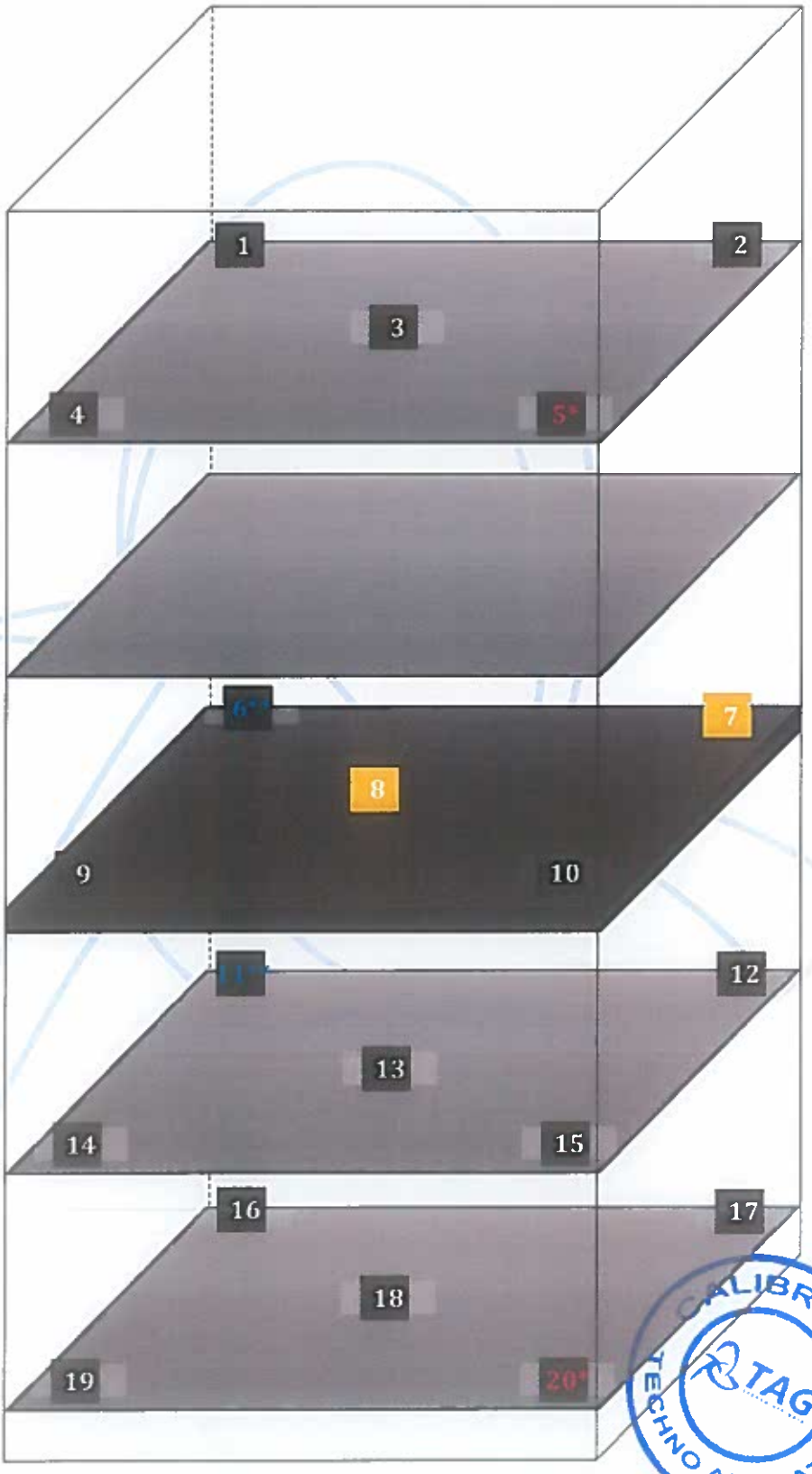
- The temperature data collected throughout the study day indicates uniformity and consistent temperature distribution across all the space of the Refrigerator.
- In the refrigerator part, location (5) and (7) have been identified as the hot and cold spots for temperature in, respectively. Since location no. (7) is as non-compliant and will be neglected in the future storage processes, the deviated location no. (6) will be considered as the cold spot for temperature as previously explained in page no. 10.
- In the freezer part, location (20) and (11) have been identified as the hot and cold spots for temperature in, respectively.
- To ensure continuous monitoring of challenging temperature conditions, we recommend installing monitoring sensors at these locations (5, 6 11, & 20) within the Refrigerator.
- In summary, the performance qualification study has been successfully conducted, confirming the reliability, accuracy, and consistency of the heat distribution within the Refrigerator . 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		
Date	11/06/2025	

CALIBRATION TAG TECHNO AIR GATE

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

he 2nd shelf is neglected in the routine storage process as per customer requirement)



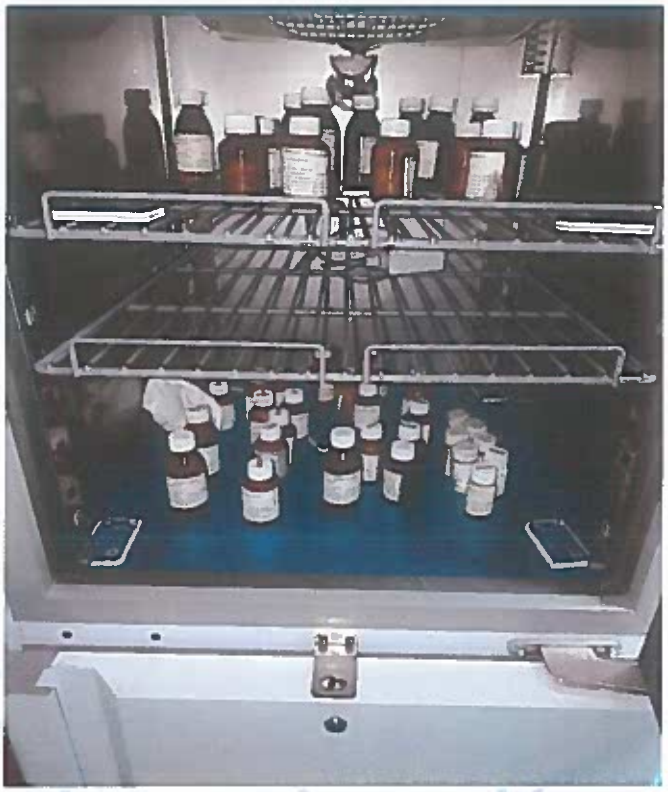
*: Hot Spot.
**: Cold Spot.

CALIBRATION TAG TECHNO AIR GATE

Note:

- The highlighted locations no. (7 & 8) are classified as non-compliant and they will be neglected in the future storage processes.

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



Refrigerator

Freezer

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.02

INTERVENTION TEST RESULTS

Content:

CALIBRATION TAG TECHNO AIR GATE

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.02.01

POWER FAILURE (BLACKOUT) TEST RESULTS

Datasheet number 01.01.02.01.01: Power Failure Test Results Data Sheets

Power Failure (Blackout) Time Data Sheet for Refrigerator (QC-REF-06)

Power Cut Period: 40 min (as per customer requirement)

Acceptance Criteria: (2 - 8) °C for Refrigerator and ((-25) to (-10)) °C for Freezer

Test Date	*Power Cut Time*	*Power Turn on Time*	*Excursion Time*	*Recovery Time*
04/06/2025	11:10 AM	11:50 AM	Refrigerator: 11:44 AM Freezer: 11:36 AM	Refrigerator: 11:52 AM Freezer: 12:06 PM
1st location to go out of the accepted criteria		5 (Refrigerator) 13 & 15 (Freezer)	*Holdover Period*	Refrigerator: 34 min Freezer: 26 min
Last location to be within accepted criteria		4 & 5 (Refrigerator) 20 (Freezer)	*Recovery Period*	Refrigerator: 2 min Freezer: 16 min

Sensor Position	Sensor S/N	Actual recorded values during the power cut: Temperature – Max. Temp (°C)	Temperature – Min. Temp (C)	Holdover Time (within range) (hr:min)	Recovery Time (return within specified range) (hr:min)
Refrigerator Part					
1.	1010149815	7.6	4.0	*from 11:10 AM to 11:50 AM*	*No excurcion occured*
2.	1010161122	7.7	4.3	*from 11:10 AM to 11:50 AM*	*No excurcion occured*
3.	1010161121	7.9	4.5	*from 11:10 AM to 11:50 AM*	*No excurcion occured*
4.	1010157523	8.1	5.0	*from 11:10 AM to 11:48 AM*	*at 11:52 AM*
5.	1010148394	8.3*	5.3	*from 11:10 AM to 11:44 AM*	*at 11:52 AM*
6.	1010157516	4.2	2.1	*from 11:10 AM to 11:50 AM*	*No excurcion occured*
7.	1010157521	4.3	1.8**	*Can't be estimated as this location was non compliant in the main cycle.*	
8.	1010157751	3.7	1.9	*Can't be estimated as this location was non compliant in the main cycle.*	
9.	1010157511	4.9	3.3	*from 11:10 AM to 11:50 AM*	*No excurcion occured*
10.	1010150014	4.8	3.0	*from 11:10 AM to 11:50 AM*	*No excurcion occured*
Freezer Part					
11.	1010161113	-7.6	-17.4**	*from 11:10 AM to 11:38 AM*	*at 12:00 PM*
12.	1010144277	-7.7	-17.2	*from 11:10 AM to 11:38 AM*	*at 12:00 PM*
13.	1010150017	-7.2*	-16.8	*from 11:10 AM to 11:36 AM*	*at 12:02 PM*
14.	1010149991	-7.5	-16.8	*from 11:10 AM to 11:38 AM*	*at 12:02 PM*
15.	1010161102	-7.3	-16.6	*from 11:10 AM to 11:36 AM*	*at 12:04 PM*

16.	1010149999	-7.7	-17.0	*from 11:10 AM to 11:40 AM*	*at 12:02 PM*
17.	1010148434	-7.8	-17.0	*from 11:10 AM to 11:40 AM*	*at 12:02 PM*
18.	1010150000	-7.9	-17.2	*from 11:10 AM to 11:40 AM*	*at 12:02 PM*
19.	1010157517	-7.7	-16.9	*from 11:10 AM to 11:40 AM*	*at 12:04 PM*
20.	1010150019	-7.3	-15.8	*from 11:10 AM to 11:38 AM*	*at 12:06 PM*

*: Maximum Temperature.
**: Minimum Temperature.

	Reviewed By (TAG)	Reviewed By (UTOPIA PHARMACEUTICALS)
Name	Ahmed Tarek	
Signature		
Date	12/06/2025	

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**
Refrigerator Part			
Minimum recorded temperature	1.8 °C	7	1010157521
Maximum recorded temperature	8.3 °C	5	1010148394
Holdover Period for Power Cut	34 min		
Recovery Period for Power Cut	2 min		
Freezer Part			
Minimum recorded temperature	-17.4 °C	11	1010161113
Maximum recorded temperature	-7.2 °C	13	1010150017
Holdover Period for Power Cut	26 min		
Recovery Period for Power Cut	16 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		
Date	11/06/2025	

CALIBRATION TAG TECHNO AIR GATE

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.02.02

DOOR OPENING TEST RESULTS

CALIBRATION TAG TECHNO AIR GATE

Datasheet number 01.01.02.02.01: Door Opening Test Results Data Sheets

Door Opening Time Data Sheet for Refrigerator (QC-REF-06)

Door Opening Period: 5 min (as per customer requirement)

Acceptance Criteria: (2 - 8) °C for Refrigerator and ((-25) to (-10)) °C for Freezer

Test Date	*Door Opening Time*	*Door Closing Time*	*Excursion Time*	*Recovery Time*
04/06/2025	01:28 PM	01:33 PM	Refrigerator: ~ 01:29 PM Freezer: ~ 01:29 PM	Refrigerator: 01:38 PM Freezer: 02:00 PM
1st location to go out of the accepted criteria		1 to 5 (Refrigerator) All locations (Freezer)	*Holdover Period*	Refrigerator: ~ 1 min Freezer: ~ 1 min
Last location to be within accepted criteria		2, 4 & 5 (Refrigerator) 20 (Freezer)	*Recovery Period*	Refrigerator: 5 min Freezer: 27 min

Sensor Position	Sensor S/N	Actual recorded values during the door opening: Temperature – Max. Temp. (C)	Temperature – Min. Temp. (°C)	Holdover Time (within range) (hr:min)	Recovery Time (return within specified range) (hr:min)
Refrigerator Part					
1.	1010149815	10.2	4.1	*from 01:28 PM to ~ 01:29 PM*	*at 01:36 PM*
2.	1010161122	11.8	4.4	*from 01:28 PM to ~ 01:29 PM*	*at 01:38 PM*
3.	1010161121	11.1	4.5	*from 01:28 PM to ~ 01:29 PM*	*at 01:36 PM*
4.	1010157523	13.4*	5.0	*from 01:28 PM to ~ 01:29 PM*	*at 01:38 PM*
5.	1010148394	12.2	5.3	*from 01:28 PM to ~ 01:29 PM*	*at 01:38 PM*
6.	1010157516	6.6	2.2	*from 01:28 PM to 01:33 PM*	*No excurcion occured*
7.	1010157521	6.6	1.9**	*Can't be estimated as this location was non compliant in the main cycle.*	
8.	1010157751	5.5	2.1	*from 01:28 PM to 01:33 PM*	*No excurcion occured*
9.	1010157511	6.3	3.5	*from 01:28 PM to 01:33 PM*	*No excurcion occured*
10.	1010150014	5.9	3.2	*from 01:28 PM to 01:33 PM*	*No excurcion occured*
Freezer Part					
11.	1010161113	1.9	-17.2**	*from 01:28 PM to ~ 01:29 PM*	*at 01:54 PM*
12.	1010144277	1.9	-17.1	*from 01:28 PM to ~ 01:29 PM*	*at 01:56 PM*
13.	1010150017	2.1	-16.6	*from 01:28 PM to ~ 01:29 PM*	*at 01:56 PM*
14.	1010149991	2.0	-16.7	*from 01:28 PM to ~ 01:29 PM*	*at 01:56 PM*

15.	1010161102	4.1*	-16.4	*from 01:28 PM to ~ 01:29 PM*	*at 01:58 PM*
16.	1010149999	0.5	-16.8	*from 01:28 PM to ~ 01:29 PM*	*at 01:54 PM*
17.	1010148434	0.7	-16.9	*from 01:28 PM to ~ 01:29 PM*	*at 01:56 PM*
18.	1010150000	0.3	-17.1	*from 01:28 PM to ~ 01:29 PM*	*at 01:54 PM*
19.	1010157517	1.1	-16.7	*from 01:28 PM to ~ 01:29 PM*	*at 01:56 PM*
20.	1010150019	2.2	-15.7	*from 01:28 PM to ~ 01:29 PM*	*at 02:00 PM*

*: Maximum Temperature.
**: Minimum Temperature.

	Reviewed By (TAG)	Reviewed By (UTOPIA PHARMACEUTICALS)
Name	Ahmed Tarek	
Signature		
Date	11/08/2025	

CALIBRATION TAG TECHNO AIR GATE

REFRIGERATOR PERFORMANCE QUALIFICATION

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**
Refrigerator Part			
Minimum recorded temperature	1.9 °C	7	1010157521
Maximum recorded temperature	13.4 °C	4	1010157523
Holdover Period for Door Opening	~ 1 min		
Recovery Period for Door Opening	5 min		
Freezer Part			
Minimum recorded temperature	-17.2 °C	11	1010161113
Maximum recorded temperature	4.1°C	15	1010161102
Holdover Period for Door Opening	~ 1 min		
Recovery Period for Door Opening	27 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		
Date	11/06/2025	

CALIBRATION TAG TECHNO AIR GATE

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

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:

CALIBRATION TAG TECHNO AIR GATE

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.04

EQUIPMENT CALIBRATION VERIFICATION

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	1010149815	Apr., 2025	Oct., 2025
2.	Data Logger	LOG TAG /HAXO-08	1010161122	Apr., 2025	Oct., 2025
3.	Data Logger	LOG TAG /HAXO-08	1010161121	Apr., 2025	Oct., 2025
4.	Data Logger	LOG TAG /HAXO-08	1010157523	Apr., 2025	Oct., 2025
5.	Data Logger	LOG TAG /HAXO-08	1010148394	Apr., 2025	Oct., 2025
6.	Data Logger	LOG TAG /HAXO-08	1010157516	Apr., 2025	Oct., 2025
7.	Data Logger	LOG TAG /HAXO-08	1010157521	Apr., 2025	Oct., 2025
8.	Data Logger	LOG TAG /HAXO-08	1010157751	Apr., 2025	Oct., 2025
9.	Data Logger	LOG TAG /HAXO-08	1010157511	Apr., 2025	Oct., 2025
10.	Data Logger	LOG TAG /HAXO-08	1010150014	Apr., 2025	Oct., 2025
11.	Data Logger	LOG TAG /HAXO-08	1010161113	Apr., 2025	Oct., 2025
12.	Data Logger	LOG TAG /HAXO-08	1010144277	Apr., 2025	Oct., 2025
13.	Data Logger	LOG TAG /HAXO-08	1010150017	Apr., 2025	Oct., 2025
14.	Data Logger	LOG TAG /HAXO-08	1010149991	Apr., 2025	Oct., 2025
15.	Data Logger	LOG TAG /HAXO-08	1010161102	Apr., 2025	Oct., 2025
16.	Data Logger	LOG TAG /HAXO-08	1010149999	Apr., 2025	Oct., 2025
17.	Data Logger	LOG TAG /HAXO-08	1010148434	Apr., 2025	Oct., 2025
18.	Data Logger	LOG TAG /HAXO-08	1010150000	Apr., 2025	Oct., 2025
19.	Data Logger	LOG TAG /HAXO-08	1010157517	Apr., 2025	Oct., 2025
20.	Data Logger	LOG TAG /HAXO-08	1010150019	Apr., 2025	Oct., 2025

	Reviewed By (TAG)	Reviewed By (UTOPIA PHARMACEUTICALS)
Name	Ahmed Tarek	
Signature		
Date	11/06/2025	

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.05

LIST OF ATTACHEMENTS

CALIBRATION TAG TECHNO AIR GATE

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)

CALIBRATION TAG TECHNO AIR GATE

	Reviewed By (TAG)	Reviewed By (UTOPIA PHARMACEUTICALS)
Name	Ahmed Tarek	
Signature		
Date	11/06/2025	

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:

	Name	Signature	Title	Company	Date
Approved by	Mohamed Hassan	M. Hass	T.O.T.L.	TAG	11/06/2025
Approved by	Abdelrahman Ramadan	A-Ramdan	P.E.	TAG	11/06/2025
Approved by	Noha Essam	NohaEssam	SR. T.O.E	TAG	11/06/2025
Approved by	Ahmed Tarek		T.M.	TAG	11/06/2025
Approved by					
Approved by					
Approved by					
Approved by					

CALIBRATION TAG TECHNO AIR GATE