



VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

WALK-IN ACCELERATED STABILITY CHAMBER

(QC-STB-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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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 and relative humidity distribution within the Stability Chamber 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 and relative humidity for each location.
 - Mean Kinetic Temperature (MKT) for each location.
 - Average temperature and relative humidity 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 and relative humidity for each location.
 - The duration it took before any deviation occurred (Holdover Period).
 - The time required for the temperature and relative humidity 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 Stability Chamber (QC-STB-04) located at UTOPIA PHARMACEUTICALS with the following description:

System Brief Description	
Description	Walk-In Accelerated Stability Chamber
Dimensions/Volume	2000 mm (w) × 2000 mm (D) × 2500 mm (H)
Manufacturing	Thermolab
Model	SG10K0M618
S.N.	495/12/20-21
Code	QC-STB-04
Acceptance Criteria	(30 ± 2) °C, (75 ± 5) %RH
Location	Stability Room-1 (LB-021)
Load Description	Half Load
Key Operating Parameters	Temperature and Relative Humidity

2.3. Associated Material and Equipment Description

Used Reference Equipment Description						
Description	No. of EDLMs	Location	Accuracy	Manufacturer	Model	Calibration Due Date
Data Logger	22	Inside Stability Chamber	± 0.5 °C, ± 5 %RH	TZONE	TEMPU03	Oct., 2025



2.4. Study Design

Heat Distribution Study Design

Controller Setting: @ 30 °C and @ 75 %RH

Acceptance Criteria: (30 ± 2) °C, (75 ± 5) %RH

Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	Half Load 200 Bottles of Levohistam Drops 550 Boxes of Chrtoreq 350 Boxes of Nanazoxid Tablets 100 Boxes of Trostic Injection 50 Boxes of Vonopravin 180 Boxes of Blokstens HCT 400 Bottles of Vit D3 Drops	02/06/2025 06:00 PM	03/06/2025 06:00 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 11:08 AM	04/06/2025 11:45 AM	37 minutes	2 minutes
2.	Door Opening	04/06/2025 01:43 PM	04/06/2025 01:48 PM	5 minutes	2 minutes



STABILITY AND PERFORMANCE OF QUALIFICATION

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:

01.01.01.01 Main Cycle No. (1) Test Results



VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

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 Stability Chamber (QC-STB-04)									
Controller Setting: @ 30 °C, @ 75 %RH					Acceptance Criteria: (30 ± 2) °C, (75 ± 5) %RH				
Load Description: Half Load					Study Period: 1 Day (24 hrs.)				
Stabilization Started at			02/06/2025 06:00 PM		Stabilization ended at			03/06/2025 06:00 PM	
Sensor Position	Sensor S/N	Actual						MKT. (°C)	Within Acceptance Criteria (YES / NO)?
		Average		Maximum		Minimum			
		Temp. (°C)	R.H (%)	T (°C)	R.H (%)	T (°C)	R.H (%)		
1.	TZ0322040119	29.7	74.5	30.0	75.0	29.3	72.9	29.7	YES
2.	TZ0323114599	29.7	73.9	30.0	74.6	29.4	72.0	29.7	YES
3.	TZ0323114414	29.8*	73.5	30.1	74.2	29.5	71.9	29.8	YES
4.	TZ0323114505	29.8*	73.1**	30.2	73.7	29.4	69.7	29.8	NO (out in RH%)
5.	TZ0322040178	29.7	74.3	30.0	75.1	29.2	69.0	29.7	NO (out in RH%)
6.	TZ0323114533	29.8*	73.3	30.2	74.0	29.2	67.5**	29.8	NO (out in RH%)
7.	TZ0323114558	29.6	73.6	30.1	74.2	29.3	72.3	29.6	YES
8.	TZ0323114520	29.7	74.3	30.1	74.8	29.4	72.8	29.7	YES
9.	TZ0323114411	29.7	73.8	30.3	74.5	29.3	72.9	29.7	YES
10.	TZ0322040200	29.7	75.7	30.0	76.4*	29.3	72.4	29.7	YES
11.	TZ0322040116	29.7	74.1	30.0	75.2	29.2	68.0	29.7	NO (out in RH%)
12.	TZ0322040167	29.7	76.1*	30.1	76.4*	29.3	74.6	29.7	YES
13.	TZ0322041016	29.7	74.7	30.4*	75.9	29.1**	73.2	29.7	YES
14.	TZ0322041088	29.7	74.6	30.0	75.2	29.5	73.5	29.7	YES
15.	TZ0322040187	29.7	74.8	29.9	75.5	29.5	72.7	29.7	YES
16.	TZ0322041094	29.7	75.3	30.0	76.1	29.5	73.4	29.7	YES
17.	TZ0322040105	29.6	74.4	29.9	75.1	29.4	71.9	29.6	YES
18.	TZ0322040172	29.7	74.1	30.1	74.6	29.4	73.1	29.7	YES
19.	TZ0323114592	29.8*	73.7	30.1	74.4	29.5	72.5	29.8	YES



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20.	TZ0322040112	29.8*	74.8	29.9	75.4	29.6	72.6	29.7	YES
21.	TZ0323114408	29.7	73.5	29.9	74.6	29.5	70.4	29.7	YES
22.	TZ0322041147	29.6**	75.5	29.9	76.0	29.3	72.6	29.6	YES
Average for Stability Chamber		29.7	74.4						

*: Maximum Temperature/Relative Humidity.

**: Minimum Temperature/Relative Humidity.

NOTES:

Locations No. (4, 5, 6 and 11) exhibited a transient deviation from the specified relative humidity threshold (75 ± 5) %RH on 03 June 2025 at 02:54 PM which appeared as a single peak in the charts. However, since their average recorded values have remained within the defined acceptable limits, these locations are not classified as non-compliant.

Name

Signature

Date

Reviewed By (TAG)

Ahmed Tarek

10/06/2025

Reviewed By (UTOPIA PHARMACEUTICALS)

STABILITY CHAMBER PERFORMANCE EVALUATION

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

- Using 22 data loggers, the performance of the Stability Chamber (QC-STB-04) has been performed with half 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	29.1 °C	13	TZ0322041016
Maximum recorded temperature	30.4 °C	13	TZ0322041016
Minimum Average recorded temperature	29.6 °C	22	TZ0322041147
Maximum Average recorded temperature	29.8 °C	3, 4, 6, 19 & 20	TZ0323114414, TZ0323114505, TZ0323114533 TZ0323114592 & TZ0322040112
Average recorded temperature	29.7 °C		
Minimum recorded relative humidity	67.5 %RH	6	TZ0323114533
Maximum recorded relative humidity	76.4 %RH	10 & 12	TZ0322040200 & TZ0322040167
Minimum Average recorded relative humidity	73.1 %RH	4	TZ0323114505
Maximum Average recorded relative humidity	76.1 %RH	12	TZ0322040167
Average recorded relative humidity	74.4 %RH		
No. of Data Loggers used for this study: 22 Data loggers			

- The temperature and relative humidity data collected throughout the study day indicates uniformity and consistent temperature and relative humidity distribution across all the space of the Stability Chamber.
- Location (4 & 6) and (22) have been identified as the hot and cold spots for temperature, respectively.
- Location (12) and (6) have been identified as the hot and cold spots for relative humidity, respectively.
- To ensure continuous monitoring of challenging temperature and relative humidity conditions, we recommend installing monitoring sensors at these locations (4, 6, 12 & 22) within the Stability Chamber.
- In summary, the performance qualification study has been successfully conducted, confirming the reliability, accuracy, and consistency of the heat distribution within the Stability Chamber. 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 PHARMACEUTICALS)

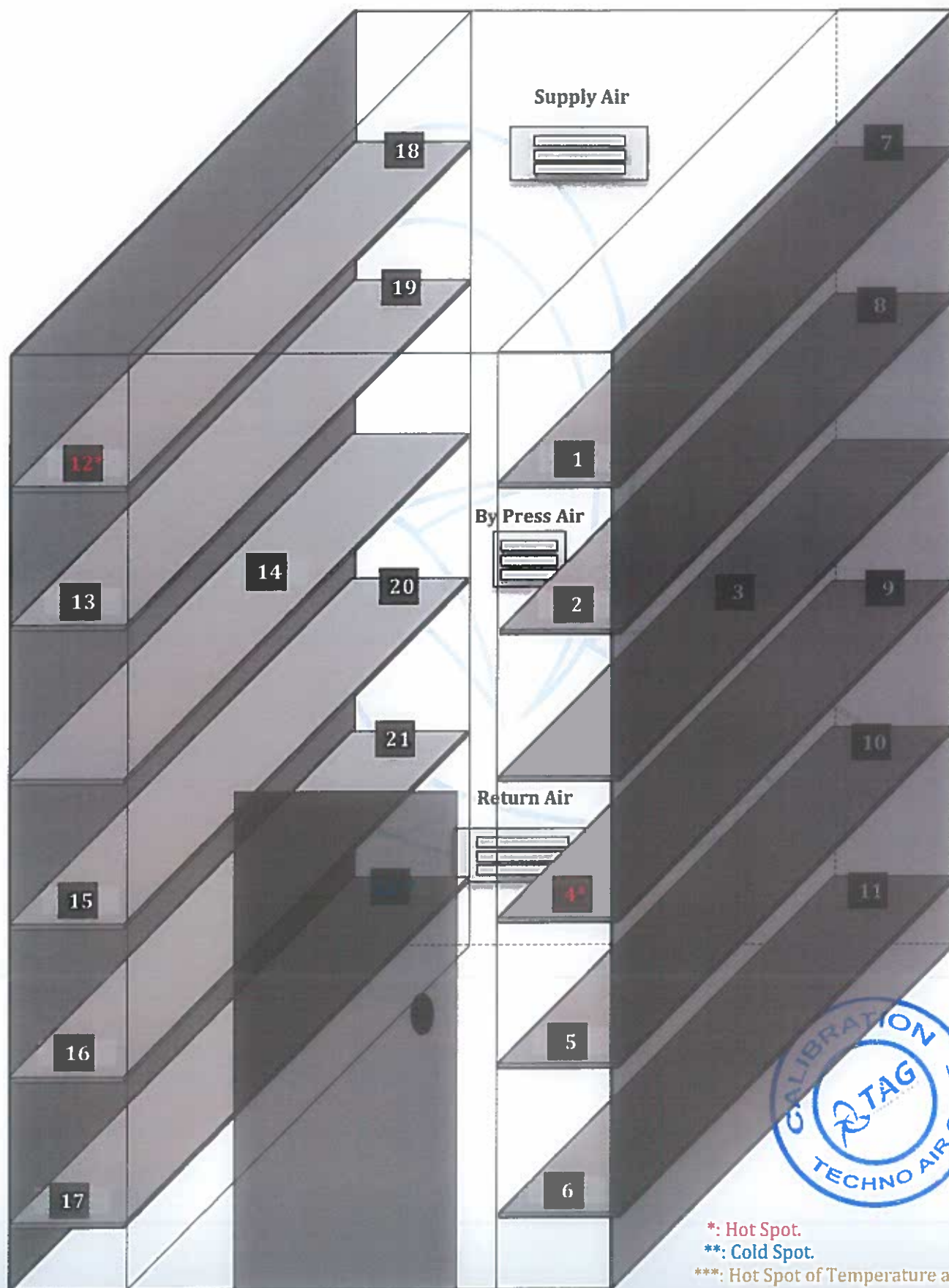
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Datasheet number 01.01.01.03: Main Cycle No. (1) layout and data loggers' distribution with worst points



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



STABILITY CHAMBER PERFORMANCE QUALIFICATION

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01
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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ANNEX 01.01

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 Stability Chamber (QC-STB-04)				
Power Cut Period: 37 min (as per customer requirement)				
Acceptance Criteria: (30 ± 2) °C, (75 ± 5) %RH				
Test Date	Power Cut Time	Power Turn on Time	Excursion Time	Recovery Time
04/06/2025	11:08 AM	11:45 AM	NA	NA
1 st location to go out of the accepted criteria		NA	Holdover Period	37 min
Last location to be within accepted criteria		NA	Recovery Period	NA
Excursion Time & Recovery Time/Period		As no location exceeded the accepted limit during the entire 30-minutes period of power failure, the excursion time and the recovery time/period cannot be estimated.		

Sensor Position	Sensor S/N	Actual recorded values during the power cut				Holdover Time (within range)	Recovery Time (return within specified range)
		Temperature		Relative Humidity			
		Max. Temp.	Min. Temp.	Max. RH	Min. RH		
		Temp. (°C)	T (°C)	RH (%)	RH (%)		
						(hr:min)	(hr:min)
1.	TZ0322040119	30.1*	29.5	74.8	73.3	from 11:08 AM to 11:45 AM	No excursion occurred
2.	TZ0323114599	29.9	29.6	74.2	73.3	from 11:08 AM to 11:45 AM	No excursion occurred
3.	TZ0323114414	29.8	29.6	74.0	73.4	from 11:08 AM to 11:45 AM	No excursion occurred
4.	TZ0323114505	29.8	29.6	73.5	73.0	from 11:08 AM to 11:45 AM	No excursion occurred
5.	TZ0322040178	29.6	29.5	74.7	74.4	from 11:08 AM to 11:45 AM	No excursion occurred
6.	TZ0323114533	29.7	29.5	73.7	73.5	from 11:08 AM to 11:45 AM	No excursion occurred
7.	TZ0323114558	30.1*	29.5	74.0	72.2**	from 11:08 AM to 11:45 AM	No excursion occurred
8.	TZ0323114520	29.9	29.5	74.6	73.5	from 11:08 AM to 11:45 AM	No excursion occurred
9.	TZ0323114411	29.8	29.6	74.5	73.5	from 11:08 AM to 11:45 AM	No excursion occurred
10.	TZ0322040200	29.6	29.5	75.8	75.5	from 11:08 AM to 11:45 AM	No excursion occurred
11.	TZ0322040116	29.6	29.5	74.5	74.3	from 11:08 AM to 11:45 AM	No excursion occurred
12.	TZ0322040167	30.1*	29.5	76.3*	74.7	from 11:08 AM to 11:45 AM	No excursion occurred
13.	TZ0322041016	29.8	29.6	75.0	74.2	from 11:08 AM to 11:45 AM	No excursion occurred
14.	TZ0322041088	29.7	29.6	74.9	74.3	from 11:08 AM to 11:45 AM	No excursion occurred
15.	TZ0322040187	29.7	29.6	74.8	74.4	from 11:08 AM to 11:45 AM	No excursion occurred



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16.	TZ0322041094	29.7	29.6	75.2	74.9	from 11:08 AM to 11:45 AM	No excursion occurred
17.	TZ0322040105	29.6	29.5	74.5	74.0	from 11:08 AM to 11:45 AM	No excursion occurred
18.	TZ0322040172	29.9	29.5	74.6	72.4	from 11:08 AM to 11:45 AM	No excursion occurred
19.	TZ0323114592	29.8	29.6	74.2	73.4	from 11:08 AM to 11:45 AM	No excursion occurred
20.	TZ0322040112	29.8	29.7	74.8	74.6	from 11:08 AM to 11:45 AM	No excursion occurred
21.	TZ0323114408	29.7	29.6	73.9	73.7	from 11:08 AM to 11:45 AM	No excursion occurred
22.	TZ0322041147	29.5	29.4**	75.7	75.4	from 11:08 AM to 11:45 AM	No excursion occurred

*: Maximum Temperature/Relative Humidity.

**: Minimum Temperature/Relative Humidity.

Reviewed By (TAG)

Name

Signature

Date



Reviewed By (UTOPIA PHARMACEUTICALS)

STABILITY CHAMBER PERFORMANCE QUALIFICATION

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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	29.4 °C	22	TZ0322041147
Maximum recorded temperature	30.1 °C	1, 7 & 12	TZ0322040119, TZ0323114558 & TZ0322040167
Minimum recorded relative humidity	72.2 %RH	7	TZ0323114558
Maximum recorded relative humidity	76.3 %RH	12	TZ0322040167
Holdover Period for Power Cut	37 min		
Recovery Period for Power Cut	As no location exceeded the accepted limit during the entire 30-minutes period of power failure, the recovery period cannot be estimated.		

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



Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Signature

Date

Ahmed Tarek

10/06/2025

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ANNEX 01.01

RESULTS DATA SHEETS

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 Stability Chamber (QC-STB-04)				
Door Opening Period: 5 min (as per customer requirement)				
Acceptance Criteria: (30 ± 2) °C, (75 ± 5) %RH				
Test Date	Door Opening Time	Door Closing Time	Excursion Time	Recovery Time
04/06/2025	01:40 PM	01:45 PM	~ 01:41 PM	01:52 PM
1 st location to go out of the accepted criteria		6 & 10	Holdover Period	~ 1 min
Last location to be within accepted criteria		2, 3, 4, 7 & 8	Recovery Period	7 min

Sensor Position	Sensor S/N	Actual recorded values during the door opening				Holdover Time (within range)	Recovery Time (return within specified range)
		Temperature		Relative Humidity			
		Max. Temp.	Min. Temp.	Max. RH	Min. RH		
		Temp. (°C)	T (°C)	RH (%)	RH (%)	{hr:min}	{hr:min}
1.	TZ0322040119	29.9*	29.4	74.2	68.7	from 01:40 PM to 01:42 PM	at 01:50 PM
2.	TZ0323114599	29.9*	29.3	74.0	67.9	from 01:40 PM to 01:42 PM	at 01:52 PM
3.	TZ0323114414	29.9*	29.2	73.9	67.2	from 01:40 PM to 01:42 PM	at 01:52 PM
4.	TZ0323114505	29.9*	29.1	73.5	65.3	from 01:40 PM to 01:42 PM	at 01:52 PM
5.	TZ0322040178	29.7	28.7	74.7	66.0	from 01:40 PM to 01:42 PM	at 01:50 PM
6.	TZ0323114533	29.9*	28.4**	73.7	63.9**	from 01:40 PM to ~ 01:41 PM	at 01:50 PM
7.	TZ0323114558	29.9*	29.4	73.4	67.9	from 01:40 PM to 01:42 PM	at 01:52 PM
8.	TZ0323114520	29.9*	29.5	74.1	68.1	from 01:40 PM to 01:42 PM	at 01:52 PM
9.	TZ0323114411	29.7	29.2	74.3	68.8	from 01:40 PM to 01:44 PM	at 01:48 PM
10.	TZ0322040200	29.7	28.7	75.8*	68.4	from 01:40 PM to ~ 01:41 PM	at 01:48 PM
11.	TZ0322040116	29.7	28.6	74.6	66.0	from 01:40 PM to 01:42 PM	at 01:50 PM
12.	TZ0322040167	29.9*	29.4	75.7	70.8	from 01:40 PM to 01:45 PM	No excursion occurred
13.	TZ0322041016	29.5	28.8	75.3	70.2	from 01:40 PM to 01:45 PM	No excursion occurred
14.	TZ0322041088	29.7	29.3	74.8	69.5	from 01:40 PM to 01:42 PM	at 01:46 PM
15.	TZ0322040187	29.7	29.3	75.0	69.7	from 01:40 PM to 01:46 PM	at 01:50 PM
16.	TZ0322041094	29.7	29.1	75.4	69.4	from 01:40 PM to 01:42 PM	at 01:48 PM



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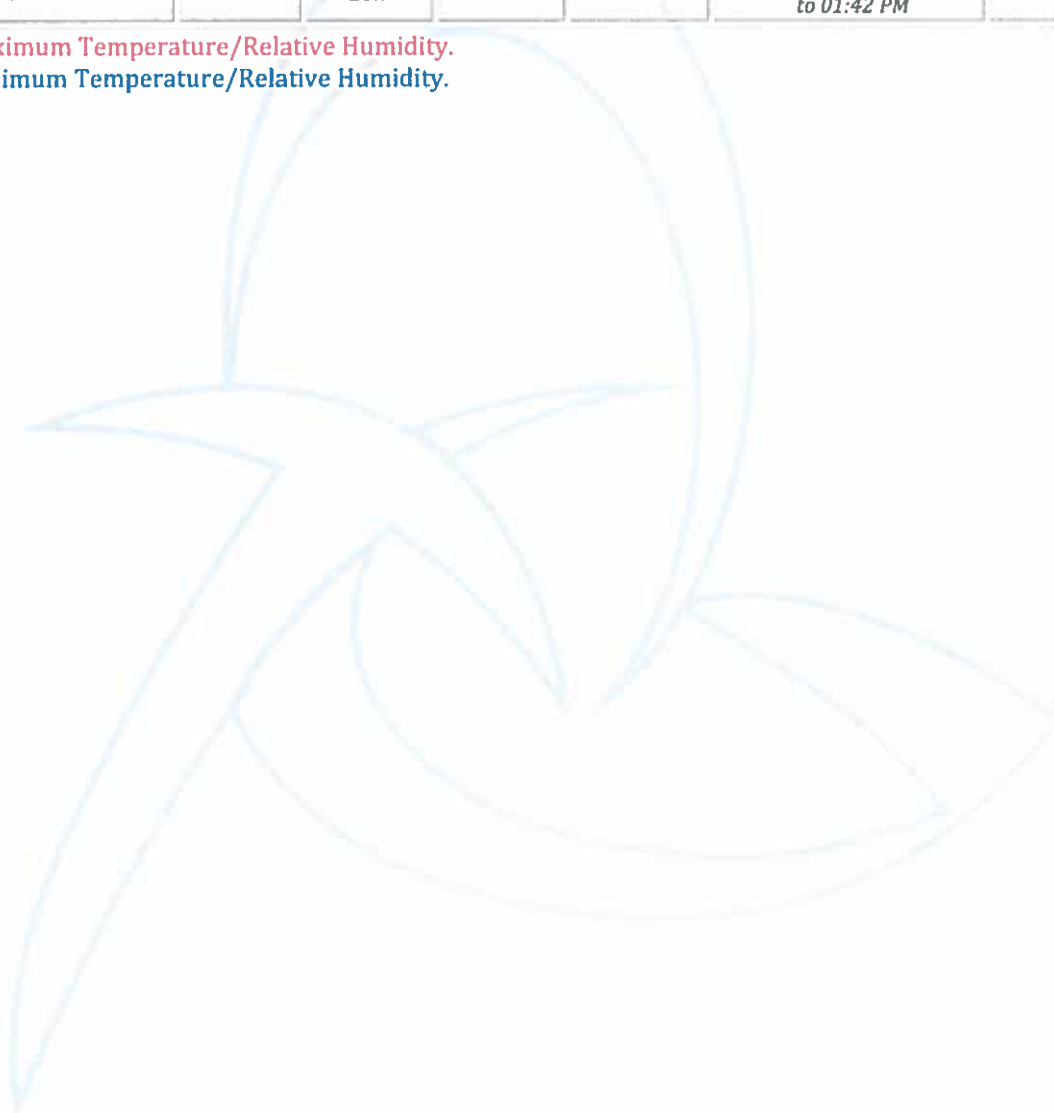
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17.	TZ0322040105	29.6	29.1	74.8	69.2	from 01:40 PM to 01:42 PM	at 01:50 PM
18.	TZ0322040172	29.8	29.3	74.0	69.0	from 01:40 PM to 01:44 PM	at 01:50 PM
19.	TZ0323114592	29.8	29.4	74.1	68.8	from 01:40 PM to 01:42 PM	at 01:50 PM
20.	TZ0322040112	29.8	29.2	74.9	69.0	from 01:40 PM to ~ 01:41 PM	at 01:48 PM
21.	TZ0323114408	29.7	29.0	74.2	67.2	from 01:40 PM to 01:42 PM	at 01:50 PM
22.	TZ0322041147	29.6	28.9	75.8*	69.3	from 01:40 PM to 01:42 PM	at 01:48 PM

*: Maximum Temperature/Relative Humidity.

** : Minimum Temperature/Relative Humidity.



STABILITY CHAMBER PERFORMANCE QUALIFICATION



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Reviewed By (UTOPIA PHARMACEUTICALS)

Name

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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	28.4 °C	6	TZ0323114533
Maximum recorded temperature	29.9 °C	1, 2, 3, 4, 6, 7, 8 & 12	TZ0322040119, TZ0323114599, TZ0323114414, TZ0323114505, TZ0322040178, TZ0323114533, TZ0323114558, TZ0323114520, TZ0323114411, TZ0322040200, TZ0322040116 & TZ0322040167
Minimum recorded relative humidity	63.9 %RH	6	TZ0323114533
Maximum recorded relative humidity	75.8 %RH	10	TZ0322040200
Holdover Period for Door Opening	~ 1 min		
Recovery Period for Door Opening	7 min		

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



Reviewed By (TAG)

Ahmed Tarek

10/06/2025

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Signature

Date

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01
RESULTS DATA SHEETS

DATA SHEET 01.01.03
DEVIATION REPORT



Jun., 2025

Rev. No.: 00

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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:

STABILITY CHAMBER PERFORMANCE QUALIFICATION

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.04

EQUIPMENT CALIBRATION VERIFICATION



Jun., 2025

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Doc. No.: PQR-M-00325

F-7.4/32
Issue Date:02/02/2025

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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	TZONE/TEMPU03	TZ0322040119	Apr., 2025	Oct., 2025
2.	Data Logger	TZONE/TEMPU03	TZ0323114599	Apr., 2025	Oct., 2025
3.	Data Logger	TZONE/TEMPU03	TZ0323114414	Apr., 2025	Oct., 2025
4.	Data Logger	TZONE/TEMPU03	TZ0323114505	Apr., 2025	Oct., 2025
5.	Data Logger	TZONE/TEMPU03	TZ0322040178	Apr., 2025	Oct., 2025
6.	Data Logger	TZONE/TEMPU03	TZ0323114533	Apr., 2025	Oct., 2025
7.	Data Logger	TZONE/TEMPU03	TZ0323114558	Apr., 2025	Oct., 2025
8.	Data Logger	TZONE/TEMPU03	TZ0323114520	Apr., 2025	Oct., 2025
9.	Data Logger	TZONE/TEMPU03	TZ0323114411	Apr., 2025	Oct., 2025
10.	Data Logger	TZONE/TEMPU03	TZ0322040200	Apr., 2025	Oct., 2025
11.	Data Logger	TZONE/TEMPU03	TZ0322040116	Apr., 2025	Oct., 2025
12.	Data Logger	TZONE/TEMPU03	TZ0322040167	Apr., 2025	Oct., 2025
13.	Data Logger	TZONE/TEMPU03	TZ0322041016	Apr., 2025	Oct., 2025
14.	Data Logger	TZONE/TEMPU03	TZ0322041088	Apr., 2025	Oct., 2025
15.	Data Logger	TZONE/TEMPU03	TZ0322040187	Apr., 2025	Oct., 2025
16.	Data Logger	TZONE/TEMPU03	TZ0322041094	Apr., 2025	Oct., 2025
17.	Data Logger	TZONE/TEMPU03	TZ0322040105	Apr., 2025	Oct., 2025
18.	Data Logger	TZONE/TEMPU03	TZ0322040172	Apr., 2025	Oct., 2025
19.	Data Logger	TZONE/TEMPU03	TZ0323114592	Apr., 2025	Oct., 2025
20.	Data Logger	TZONE/TEMPU03	TZ0322040112	Apr., 2025	Oct., 2025
21.	Data Logger	TZONE/TEMPU03	TZ0323114408	Apr., 2025	Oct., 2025
22.	Data Logger	TZONE/TEMPU03	TZ0322041147	Apr., 2025	Oct., 2025

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Signature

Date



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Vol 01) Annex 01.01)

Results Data Sheets

Walk-In Accelerated Stability Chamber (QC-STB-04)



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VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.05

LIST OF ATTACHEMENTS



STABILITY CHAMBER PERFORMANCE QUALIFICATION

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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 PHARMACEUTICALS)

Name

Signature

Date

18/06/2025

STANDARD OPERATING PROCEDURE FOR MANUFACTURING

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

