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VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

RETAINED SAMPLE ROOM FOR RAW MATERIAL

(LB-025)

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

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1.	00	NA	Original	11/06/2025

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 Retained Sample Room 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 Retained Sample Room (LB-025) located at UTOPIA PHARMACEUTICALS with the following description:

System Brief Description	
Description	Retained Sample Room for Raw Material
Dimensions/Volume	5.3 m (L) x 5.0 m (W) x 2.7 m (H)
Code	LB-025
Acceptance Criteria	NMT 25 °C, NMT 65 %RH
Location	Raw Material Warehouse
Load Description	Full 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	27	Inside Retained Sample Room	± 0.5 °C, ± 5 %RH	TZONE	TEMPU03	Oct, 2025
Data Logger	1	Outside Retained Sample Room (Ambient)	± 0.5 °C, ± 5 %RH	TZONE	TEMPU03	Oct, 2025



RETAINED SAMPLE ROOM PERFORMANCE QUALIFICATION

2.4. Study Design

Heat Distribution Study Design					
Controller Setting: @25 °C and RH% controlled with Heaters					
Acceptance Criteria: NMT 25 °C, NMT 65 %RH					
Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	Full Load (Packaging material: 9 Columns (of the 9 racks with 5 shelves) & (the 3 columns of the 2 racks with 6 shelves). Raw materials: 10 Columns of the 9 racks with 5 shelves are filled with 128 bottle/shelf. 10 (columns) * 5 (shelves) * 128 = 6400 bottles)	02/06/2025 05:36 PM	03/06/2025 05:36 PM	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 11:45 AM	04/06/2025 12:15 PM	30 minutes	2 minutes
2.	Door Opening	04/06/2025 01:33 PM	04/06/2025 01:38 PM	5 minutes	2 minutes



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



RETENTION SAMPLE ROOM PERFORMANCE OF CALIBRATION

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01.01

MAIN CYCLE NO. (I) TEST RESULTS



RETAINED SAMPLE ROOM PERFORMANCE QUALIFICATION

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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 Retained Sample Room (LB-025)									
Controller Setting: @ 25 °C, RH% controlled with Heaters.					Acceptance Criteria: NMT 25 °C, NMT 65 %RH				
Load Description: Full Load					Study Period: 24 hrs.				
Stabilization Started at			02/06/2025 05:36 PM			Stabilization ended at		03/06/2025 05:36 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.	TZ0322040180	23.1	60.4	23.2	61.8	22.8	57.6	23.1	YES
2.	TZ0322041196	23.3	60.8	23.4	62.1	23.0	58.0	23.3	YES
3.	TZ0322041188	24.0*	58.8	24.1*	60.3	23.8	56.1	24.0	YES
4.	TZ0322040169	23.2	59.9	23.3	61.4	23.1	56.6	23.2	YES
5.	TZ0322041001	23.1	61.3	23.3	62.8	22.9	58.2	23.1	YES
6.	TZ0322040129	23.4	60.8	23.5	62.1	23.3	57.6	23.4	YES
7.	TZ0322041071	22.6	64.4	22.7	65.7	22.3	60.8	22.6	NO (out in RH%)
8.	TZ0322040149	22.6	60.3	22.7	61.8	22.4	56.9	22.6	YES
9.	TZ0323114418	22.9	60.9	23.1	62.2	22.7	57.5	22.9	YES
10.	TZ0323114544	22.9	59.5	23.0	60.9	22.6	56.1	22.9	YES
11.	TZ0322040121	22.8	61.8	22.9	63.1	22.6	59.2	22.8	YES
12.	TZ0323114578	23.3	59.4	23.5	60.7	23.2	56.1	23.3	YES
13.	TZ0323114516	23.0	59.9	23.2	61.1	22.8	56.4	23.0	YES
14.	TZ0323114412	23.2	59.5	23.3	60.9	23.0	56.4	23.2	YES
15.	TZ0323114431	23.6	57.8**	23.7	59.2	23.4	54.7**	23.6	YES
16.	TZ0323114577	23.3	59.4	23.4	60.6	23.0	56.0	23.3	YES
17.	TZ0323114565	23.0	59.2	23.1	60.5	22.8	56.0	23.0	YES
18.	TZ0323114540	23.8	58.7	23.9	60.0	23.6	55.4	23.8	YES
19.	TZ0322041093	22.5**	64.6*	22.7	65.9*	22.2**	61.2	22.5	NO (out in RH%)
20.	TZ0323114535	22.7	62.6	22.8	63.9	22.3	59.4	22.7	YES
21.	TZ0323114527	22.9	59.2	23.0	60.5	22.6	56.4	22.9	YES



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22.	TZ0322040131	23.0	63.8	23.2	65.0	22.7	60.5	23.0	YES
23.	TZ0323114407	23.1	59.0	23.2	60.4	22.8	56.2	23.1	YES
24.	TZ0322040102	23.5	60.8	23.6	61.9	23.2	58.1	23.5	YES
25.	TZ0322040199	23.7	59.5	24.0	60.8	23.4	56.5	23.7	YES
26.	TZ0323114503	23.6	58.6	23.8	59.8	23.2	55.4	23.6	YES
27.	TZ0322040111	23.7	58.5	23.9	60.1	23.5	56.2	23.7	YES
Amb.	TZ0322040878	21.3	65.7	21.8	66.5	20.4	64.4	21.3	-
Average for Retained Sample Room		23.2	60.4						

*: Maximum Temperature/Relative Humidity.

** : Minimum Temperature/Relative Humidity.

NOTES:

- Locations No. (7 and 19) exhibited a transient deviation from the specified relative humidity threshold (NMT 65%) during the period spanning from 02 June 2025 at 09:02 PM to 03 June 2025 at 09:38 AM. However, since their average recorded values have remained within the defined acceptable limits, these locations are not classified as non-compliant. To ensure continued compliance and thermal stability, we recommend installing monitoring sensors at these locations for continuous assessment of heat distribution during the routine work.

Reviewed By (TAG)

Name

Ahmed Tarek

Signature

Date

11/06/2025

Reviewed By (UTOPIA PHARMACEUTICALS)



RETAINED SAMPLE ROOM PERFORMANCE EVALUATION

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

- Using 28 data loggers, the performance of the Retained Sample Room (LB-025) 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	22.2 °C	19	TZ0322041093
Maximum recorded temperature	24.1 °C	3	TZ0322041188
Minimum Average recorded temperature	22.5 °C	19	TZ0322041093
Maximum Average recorded temperature	24.0 °C	3	TZ0322041188
Average recorded temperature	23.2 °C		
Minimum recorded relative humidity	54.7 %RH	15	TZ0323114431
Maximum recorded relative humidity	65.9 %RH	19	TZ0322041093
Minimum Average recorded relative humidity	57.8 %RH	15	TZ0323114431
Maximum Average recorded relative humidity	64.6 %RH	19	TZ0322041093
Average recorded relative humidity	60.4 %RH		
No. of Data Loggers used for this study: 28 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 Retained Sample Room.
- Location (3) and (19) have been identified as the hot and cold spots for temperature, respectively.
- Location (19) and (15) have been identified as the hot and cold spots for relative humidity, respectively. Also, the deviated location no. (7) will be considered as a hot spot for relative humidity as previously explained in page no. 10.
- To ensure continuous monitoring of challenging temperature and relative humidity conditions, we recommend installing monitoring sensors at these locations (3, 7, 15 & 19) within the Retained Sample Room.
- In summary, the performance qualification study has been successfully conducted, confirming the reliability, accuracy, and consistency of the heat distribution within the Retained Sample Room. 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)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

11/06/2025



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

Location No.		Rack No.	Level	Serial number
1.	1	C1A	H	TZ0322040180
2.		C3A	M	TZ0322041196
3.		C5A	L	TZ0322041188*
4.	2	A1A	H	TZ0322040169
5.		A3A	M	TZ0322041001
6.		A5A	L	TZ0322040129
7.	3	B1C	H	TZ0322041071
8.		B3C	M	TZ0322040149
9.		B5C	L	TZ0323114418
10.	4	D1B	H	TZ0323114544
11.		D3B	M	TZ0322040121
12.		D5B	L	TZ0323114578
13.	5	E1A	H	TZ0323114516
14.		E3A	M	TZ0323114412
15.		E5A	L	TZ0323114431**
16.	6	E1B	H	TZ0323114577
17.		E3B	M	TZ0323114565
18.		E5B	L	TZ0323114540
19.	7	H1A	H	TZ0322041093***
20.		H3A	M	TZ0323114535
21.		H5A	L	TZ0323114527
22.	8	G1C	H	TZ0322040131
23.		G4C	M	TZ0323114407
24.		G6C	L	TZ0322040102
25.	9	G1A	H	TZ0322040199
26.		G4A	M	TZ0323114503
27.		G6A	L	TZ0322040111
28.	Ambient			TZ0322040878

*: Hot Spot of Temperature.

** : Cold Spot of Relative Humidity.

***: Hot Spot of Relative Humidity and Cold Spot of Temperature.



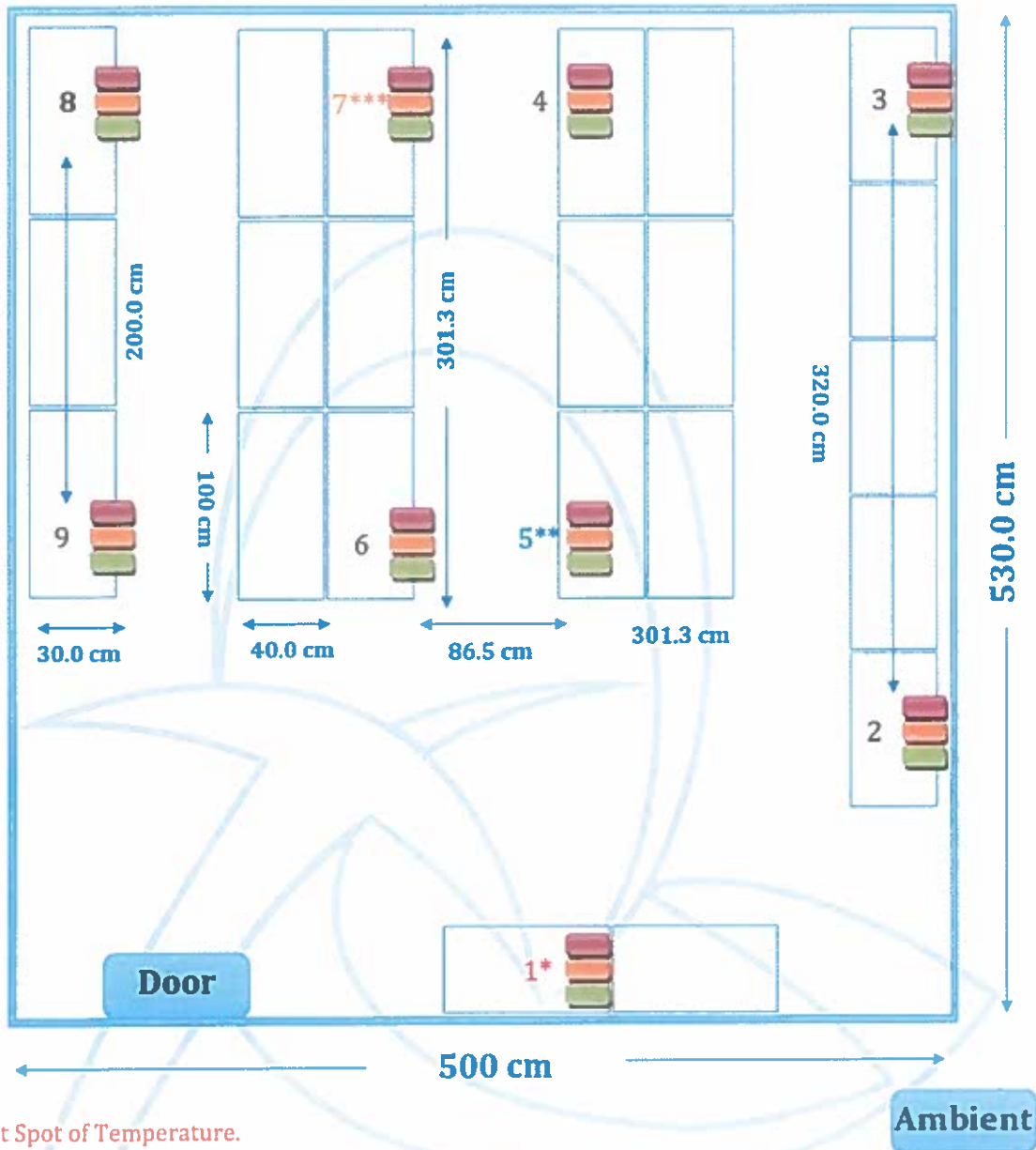
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*: Hot Spot of Temperature.

** : Cold Spot of Relative Humidity.

***: Hot Spot of Relative Humidity and Cold Spot of Temperature.

AHU	Controller Setting	
	(°C)	%RH
QC-AHU-02	25	Heaters

⌚ Dimensions of the retained sample room is 530 cm (L) x 500 cm (W) x 270 cm (H).

⌚ At Length: The distance between every dataloggers at right side is 320.0 cm.

⌚ At width: The distance between every dataloggers at right side is 200.0 cm.

- High Level at shelf 2 and 1 (80 cm from Medium Level).
- Medium Level at shelf 4 and 3 (80 cm from Ground).
- Low Level at shelf 6 and 5 (Ground Level).



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



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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 |



RETAINED SAMPLE ROOM PERFORMANCE QUALIFICATION

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

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 Retained Sample Room (LB-025)				
Power Cut Period: 30 min (as per customer requirement)				
Acceptance Criteria: NMT 25 °C, NMT 65 %RH				
Test Date	Power Cut Time	Power Turn on Time	Excursion Time	Recovery Time
04/06/2025	11:45 AM	12:15 PM	NA	NA
1 st location to go out of the accepted criteria		NA	Holdover Period	30 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. R.H.	Min. R.H.		
		Temp. (°C)	T (°C)	R.H. (%)	R.H. (%)	(hr:min)	(hr:min)
1.	TZ0322040180	23.8	23.0	61.7	60.7	From 11:45 AM to 12:15 PM	No excursion occurred
2.	TZ0322041196	23.6	23.2	61.5	61.0	From 11:45 AM to 12:15 PM	No excursion occurred
3.	TZ0322041188	24.1*	24.0	59.8	59.6	From 11:45 AM to 12:15 PM	No excursion occurred
4.	TZ0322040169	23.5	23.3	60.7	60.3	From 11:45 AM to 12:15 PM	No excursion occurred
5.	TZ0322041001	23.3	23.1	61.8	61.4	From 11:45 AM to 12:15 PM	No excursion occurred
6.	TZ0322040129	23.7	23.6	60.8	60.6	From 11:45 AM to 12:15 PM	No excursion occurred
7.	TZ0322041071	22.8	22.6	64.4	64.1	From 11:45 AM to 12:15 PM	No excursion occurred
8.	TZ0322040149	22.7	22.6	62.8	62.6	From 11:45 AM to 12:15 PM	No excursion occurred
9.	TZ0323114418	23.1	22.9	61.6	61.3	From 11:45 AM to 12:15 PM	No excursion occurred
10.	TZ0323114544	23.3	22.9	60.2	59.6	From 11:45 AM to 12:15 PM	No excursion occurred
11.	TZ0322040121	23.0	22.8	62.9	62.6	From 11:45 AM to 12:15 PM	No excursion occurred
12.	TZ0323114578	23.7	23.4	59.6	59.3	From 11:45 AM to 12:15 PM	No excursion occurred
13.	TZ0323114516	23.4	23.0	60.4	59.8	From 11:45 AM to 12:15 PM	No excursion occurred
14.	TZ0323114412	23.4	23.1	60.3	60.1	From 11:45 AM to 12:15 PM	No excursion occurred
15.	TZ0323114431	23.9	23.7	58.3	58.1**	From 11:45 AM to 12:15 PM	No excursion occurred

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16.	TZ0323114577	23.5	23.2	60.2	59.7	From 11:45 AM to 12:15 PM	No excursion occurred
17.	TZ0323114565	23.2	23.0	60.0	59.8	From 11:45 AM to 12:15 PM	No excursion occurred
18.	TZ0323114540	24.0	23.9	58.8	58.6	From 11:45 AM to 12:15 PM	No excursion occurred
19.	TZ0322041093	22.9	22.5**	64.5*	64.2	From 11:45 AM to 12:15 PM	No excursion occurred
20.	TZ0323114535	22.9	22.6	63.0	62.7	From 11:45 AM to 12:15 PM	No excursion occurred
21.	TZ0323114527	23.1	22.9	60.0	59.8	From 11:45 AM to 12:15 PM	No excursion occurred
22.	TZ0322040131	23.2	22.8	63.6	63.1	From 11:45 AM to 12:15 PM	No excursion occurred
23.	TZ0323114407	23.2	23.1	59.9	59.6	From 11:45 AM to 12:15 PM	No excursion occurred
24.	TZ0322040102	23.6	23.3	61.1	60.9	From 11:45 AM to 12:15 PM	No excursion occurred
25.	TZ0322040199	24.0	23.4	61.0	60.3	From 11:45 AM to 12:15 PM	No excursion occurred
26.	TZ0323114503	23.8	23.5	59.2	58.9	From 11:45 AM to 12:15 PM	No excursion occurred
27.	TZ0322040111	23.8	23.7	59.8	59.6	From 11:45 AM to 12:15 PM	No excursion occurred
Amb.	TZ0322040878	22.3	21.0	67.5	66.0	--	

*: Maximum Temperature/Relative Humidity.

** : Minimum Temperature/Relative Humidity.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

11/06/2025



RETAINED SAMPLE ROOM PERFORMANCE EVALUATION

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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	22.5 °C	19	TZ0322041093
Maximum recorded temperature	24.1 °C	3	TZ0322041188
Minimum recorded relative humidity	58.1 %RH	15	TZ0323114431
Maximum recorded relative humidity	64.5 %RH	19	TZ0322041093
Holdover Period for Power Cut	30 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 (UTOPIAPHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

11/06/2025



RETAINED SAMPLE ROOM PERFORMANCE DOCUMENTATION

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.02.02

DOOR OPENING TEST RESULTS



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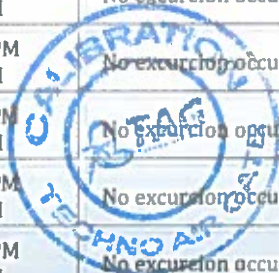
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Datasheet number 01.01.02.02.01: Door Opening Test Results Data Sheets

Door Opening Time Data Sheet for Retained Sample Room (LB-025)				
Door Opening Period: 5 min (as per customer requirement)				
Acceptance Criteria: NMT 25 °C, NMT 65 %RH				
Test Date	Door Opening Time	Door Closing Time	Excursion Time	Recovery Time
04/06/2025	01:33 PM	01:38 PM	NA	NA
1 st location to go out of the accepted criteria		NA	Holdover Period	5 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 5-minutes period of door opening, the excursion time and the recovery time/period cannot be estimated.		

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. R.H.	Min. R.H.		
		Temp. (°C)	T (°C)	R.H. (%)	R.H. (%)	(hr:min)	(hr:min)
1.	TZ0322040180	23.2	23.1	59.9	59.6	From 01:33 PM to 01:38 PM	No excursion occurred
2.	TZ0322041196	23.4	23.3	59.8	59.4	From 01:33 PM to 01:38 PM	No excursion occurred
3.	TZ0322041188	23.5	23.0	59.1	54.7	From 01:33 PM to 01:38 PM	No excursion occurred
4.	TZ0322040169	23.3	23.2	59.1	58.8	From 01:33 PM to 01:38 PM	No excursion occurred
5.	TZ0322041001	23.2	23.1	60.4	59.9	From 01:33 PM to 01:38 PM	No excursion occurred
6.	TZ0322040129	23.6	23.4	59.1	56.2	From 01:33 PM to 01:38 PM	No excursion occurred
7.	TZ0322041071	22.7	22.6	62.7	62.3	From 01:33 PM to 01:38 PM	No excursion occurred
8.	TZ0322040149	22.7	22.6	61.1	60.8	From 01:33 PM to 01:38 PM	No excursion occurred
9.	TZ0323114418	23.0	22.9	59.8	59.4	From 01:33 PM to 01:38 PM	No excursion occurred
10.	TZ0323114544	23.0	22.9	58.4	58.0	From 01:33 PM to 01:38 PM	No excursion occurred
11.	TZ0322040121	22.9	22.8	61.0	60.4	From 01:33 PM to 01:38 PM	No excursion occurred
12.	TZ0323114578	23.4	23.4	57.6	56.0	From 01:33 PM to 01:38 PM	No excursion occurred
13.	TZ0323114516	23.2	23.1	58.2	57.9	From 01:33 PM to 01:38 PM	No excursion occurred
14.	TZ0323114412	23.2	23.2	58.2	57.2	From 01:33 PM to 01:38 PM	No excursion occurred
15.	TZ0323114431	23.6	23.4	56.8	53.9**	From 01:33 PM to 01:38 PM	No excursion occurred



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16.	TZ0323114577	23.3	23.3	58.1	57.8	From 01:33 PM to 01:38 PM	No excursion occurred
17.	TZ0323114565	23.1	23.0	58.0	57.0	From 01:33 PM to 01:38 PM	No excursion occurred
18.	TZ0323114540	23.8	23.5	57.4	54.5	From 01:33 PM to 01:38 PM	No excursion occurred
19.	TZ0322041093	22.6	22.4**	62.9*	62.5	From 01:33 PM to 01:38 PM	No excursion occurred
20.	TZ0323114535	22.7	22.6	61.2	60.7	From 01:33 PM to 01:38 PM	No excursion occurred
21.	TZ0323114527	23.0	22.9	58.3	57.8	From 01:33 PM to 01:38 PM	No excursion occurred
22.	TZ0322040131	23.1	23.0	61.5	61.1	From 01:33 PM to 01:38 PM	No excursion occurred
23.	TZ0323114407	23.3	23.2	58.0	57.4	From 01:33 PM to 01:38 PM	No excursion occurred
24.	TZ0322040102	23.5	23.4	59.2	58.4	From 01:33 PM to 01:38 PM	No excursion occurred
25.	TZ0322040199	23.9*	23.8	58.4	58.0	From 01:33 PM to 01:38 PM	No excursion occurred
26.	TZ0323114503	23.7	23.6	57.1	55.9	From 01:33 PM to 01:38 PM	No excursion occurred
27.	TZ0322040111	23.8	23.7	57.7	56.7	From 01:33 PM to 01:38 PM	No excursion occurred
Amb.	TZ0322040878	21.5	21.2	66.1	65.4	--	

*: Maximum Temperature/Relative Humidity.

** : Minimum Temperature/Relative Humidity.

Reviewed By (TAG)

Reviewed By (UTOPIA PHARMACEUTICALS)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

11/06/2025



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	22.4 °C	19	TZ0322041093
Maximum recorded temperature	23.9 °C	25	TZ0322040199
Minimum recorded relative humidity	53.9 %RH	15	TZ0323114431
Maximum recorded relative humidity	62.9 %RH	19	TZ0322041093
Holdover Period for Door Opening	5 min		
Recovery Period for Door Opening	As no location exceeded the accepted limit during the entire 5-minutes period of door opening, the recovery period cannot be estimated.		

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

Reviewed By (TAG)

Name

Ahmed Tarek

Signature

Date

11/06/2025

Reviewed By (UTOPIA PHARMACEUTICALS)



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:



VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

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	TZONE/TEMPU03	TZ0322040180	Apr., 2025	Oct., 2025
2.	Data Logger	TZONE/TEMPU03	TZ0322041196	Apr., 2025	Oct., 2025
3.	Data Logger	TZONE/TEMPU03	TZ0322041188	Apr., 2025	Oct., 2025
4.	Data Logger	TZONE/TEMPU03	TZ0322040169	Apr., 2025	Oct., 2025
5.	Data Logger	TZONE/TEMPU03	TZ0322041001	Apr., 2025	Oct., 2025
6.	Data Logger	TZONE/TEMPU03	TZ0322040129	Apr., 2025	Oct., 2025
7.	Data Logger	TZONE/TEMPU03	TZ0322041071	Apr., 2025	Oct., 2025
8.	Data Logger	TZONE/TEMPU03	TZ0322040149	Apr., 2025	Oct., 2025
9.	Data Logger	TZONE/TEMPU03	TZ0323114418	Apr., 2025	Oct., 2025
10.	Data Logger	TZONE/TEMPU03	TZ0323114544	Apr., 2025	Oct., 2025
11.	Data Logger	TZONE/TEMPU03	TZ0322040121	Apr., 2025	Oct., 2025
12.	Data Logger	TZONE/TEMPU03	TZ0323114578	Apr., 2025	Oct., 2025
13.	Data Logger	TZONE/TEMPU03	TZ0323114516	Apr., 2025	Oct., 2025
14.	Data Logger	TZONE/TEMPU03	TZ0323114412	Apr., 2025	Oct., 2025
15.	Data Logger	TZONE/TEMPU03	TZ0323114431	Apr., 2025	Oct., 2025
16.	Data Logger	TZONE/TEMPU03	TZ0323114577	Apr., 2025	Oct., 2025
17.	Data Logger	TZONE/TEMPU03	TZ0323114565	Apr., 2025	Oct., 2025
18.	Data Logger	TZONE/TEMPU03	TZ0323114540	Apr., 2025	Oct., 2025
19.	Data Logger	TZONE/TEMPU03	TZ0322041093	Apr., 2025	Oct., 2025
20.	Data Logger	TZONE/TEMPU03	TZ0323114535	Apr., 2025	Oct., 2025
21.	Data Logger	TZONE/TEMPU03	TZ0323114527	Apr., 2025	Oct., 2025
22.	Data Logger	TZONE/TEMPU03	TZ0322040131	Apr., 2025	Oct., 2025
23.	Data Logger	TZONE/TEMPU03	TZ0323114407	Apr., 2025	Oct., 2025
24.	Data Logger	TZONE/TEMPU03	TZ0322040102	Apr., 2025	Oct., 2025



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25.	Data Logger	TZONE/TEMPU03	TZ0322040199	Apr., 2025	Oct., 2025
26.	Data Logger	TZONE/TEMPU03	TZ0323114503	Apr., 2025	Oct., 2025
27.	Data Logger	TZONE/TEMPU03	TZ0322040111	Apr., 2025	Oct., 2025
28.	Data Logger	TZONE/TEMPU03	TZ0322040878	Apr., 2025	Oct., 2025



RETAINED SAMPLE ROOM PERFORMANCE EVALUATION

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



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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)

Name

Ahmed Tarek

Signature

Ahmed Tarek

Date

11/06/2025

Reviewed By (UTOPIA PHARMACEUTICALS)



RETAINED SAMPLE ROOM PERFORMANCE QUALIFICATION

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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	11/06/2025
	Name	Signature	Title	Company	Date
Approved by	Abdelrahman Attito	<i>A. Attito</i>	P.E.	TAG	11/06/2025
	Name	Signature	Title	Company	Date
Approved by	Noha Essam	<i>Noha Essam</i>	SR. T.O.E	TAG	11/06/2025
	Name	Signature	Title	Company	Date
Approved by	Ahmed Tarek	<i>Ahmed Tarek</i>	T.M.	TAG	11/06/2025
	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



RETAINED SAMPLE ROOM PERFORMANCE QUALIFICATION