



VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

COLD ROOM

OF

DR REDA PHARMACY STORE

KAFR AL-SHIEKHA

CLIENT:



QUALIFICATION PROVIDER:



Package Content:

VOL-01 Performance Qualification Protocol

Annex-01.01) Results Data Sheets

Annex-01.02) Turn Over Package (Attachments)





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 2 of 19

Table of Content

	Page
1. REPORT REVIEW AND APPROVAL	3
2. INTRODUCCION	4
2.1. Report Purpose	4
2.2. System Brief Description	5
2.3. Associated Material and Equipment Description	5
2.4. Study Design	6
3. RESULTS DATA SHEETS	7
DATA SHEET (01.01.01) MAIN CYCLE TEST RESULTS	7
01.01.01.01) MAIN CYCLE NO. (1) TEST RESULTS	8
01.01.01.01.01) Main Cycle No. (1) Test Results Data Sheets	9
01.01.01.01.02) Main Cycle No. (1) Conclusion and Recommendation	10
01.01.01.01.03) Main Cycle No. (1) Layout and data loggers' distribution with worst points	11
01.01.01.01.04) Main Cycle No. (1) Qualification Photos	12
DATA SHEET (01.01.02) DEVIATION REPORT	13
01.01.02.01) Deviation Report	14
DATA SHEET (01.01.03) EQUIPMENT CALIBRATION VERIFICATION	15
01.01.03.01) Reference Instruments Calibration Verification	16
DATA SHEET (01.01.04) LIST OF ATTACHEMENTS	17
01.01.04.01) List of Attachments	18
Final Review And Approval	19





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 3 of 19

1. REPORT REVIEW AND APPROVAL

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DR REDA PHARMACY STORE Approver(s)

Name	Title	Company	Date	Signature

Change History

No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	30-06-2025

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





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 4 of 19

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 COLD ROOM located at DR REDA PHARMACY STORE. 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).



COLD ROOM PERFORMANCE QUALIFICATION



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 5 of 19

2.2. System Brief Description

The scope of this report intends to cover the performance qualification results of COLD ROOM () located at DR REDA PHARMACY STORE with the following description:

System Brief Description	
Description	Cold Room
Dimensions/Volume	--
Manufacturing	NA
Model	NA
S.N.	NA
Code	--
Acceptance Criteria	(2 - 8) °C
Location	Warehouse
Load Description	Loaded
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	12	Inside COLD ROOM	± 0.5 °C	LOG TAG	HAXO-08	Oct., 2025





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 6 of 19

2.4. Study Design

Heat Distribution Study Design

Controller Setting: @ 4.0 °C

Acceptance Criteria: (2 - 8) °C

Cycle No.	Load Description	Start Date	Stop Date	Sampling Period	Sample Frequency
1.	Full Load	26/06/2025 02:00 PM	29/06/2025 02:00 PM	3 Days (72 hrs.)	2 minutes



COLD ROOM PERFORMANCE QUALIFICATION



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 7 of 19

1. 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. (I) Test Results



COLD ROOM PERFORMANCE QUALIFICATION



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 8 of 19

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01.01

MAIN CYCLE NO. (1) TEST RESULTS



C O L D R O O M P E R F O R M A N C E Q U A L I F I C A T I O N



Vol 01) Annex 01.01) Results Data Sheets COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 9 of 19

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

Heat Distribution Study Data Sheet for COLD ROOM

Controller Setting: @ 4.0 °C

Acceptance Criteria: (2 - 8) °C

Load Description: Loaded

Stabilization Started at

26/06/2025
02:00 PM

Stabilization ended at

29/06/2025
02:00 PM

Sensor Position	Sensor S/N	Actual			MKT. [°C]	Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum		
		Temp. [°C]	Temp. [°C]	Temp. [°C]		
1.	1010148405	5.3	9.1	2.8	5.3	YES
2.	1010161123	5.2	11.9	2.9	5.3	YES
3.	1010148434	4.8**	12.8*	1.1**	5.1	YES
4.	1010148403	5.5	12.2	3.3	5.6	YES
5.	1010157753	5.2	10.9	2.9	5.3	YES
6.	1010149993	5.2	9.4	2.9	5.3	YES
7.	1010149815	5.1	11.4	2.5	5.2	YES
8.	1010148421	5.3	9.5	3.3	5.4	YES
9.	1010157757	5.1	9.0	2.6	5.2	YES
10.	1010148440	5.0	9.5	2.7	5.0	YES
11.	1010161113	5.8*	11.7	3.8	5.9	YES
12.	1010148407	5.4	10.1	3.2	5.5	YES
Average for COLD ROOM		5.2				

*: Maximum Temperature. **: Minimum Temperature.

NOTES

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."

Since, MKT calculated value has remained within the defined acceptable limits, these locations are 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.



Reviewed By (TAG)

Reviewed By (DR REDA PHARMACY STORE)

Name

Ahmed Tarek

Signature

Date

30-06-2025



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 10 of 19

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

- Using 12 data loggers, the performance of the COLD ROOM 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 72-hours period. All obtained values are not rounded.

Results Summary			
Measurements	Actual	Location	Sensor
Minimum recorded temperature	1.1 °C	3	1010148434
Maximum recorded temperature	12.8 °C	3	1010148434
Minimum Average recorded temperature	4.8 °C	3	1010148434
Maximum Average recorded temperature	5.8 °C	11	1010161113
Average recorded temperature	5.2 °C		

No. of Data Loggers used for this study: 12 Data loggers

- The temperature data collected throughout the study day indicates uniformity and consistent temperature distribution across all the space of the COLD ROOM .
- In the COLD ROOM part, location (11) and (3) have been identified as the hot and cold spots for temperature in, respectively.
- In summary, the performance qualification study has been successfully conducted, confirming the reliability, accuracy, and consistency of the heat distribution within the COLD 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 (DR REDA PHARMACY STORE)

Name

Ahmed Tarek

Signature

Date

30-06-2025





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

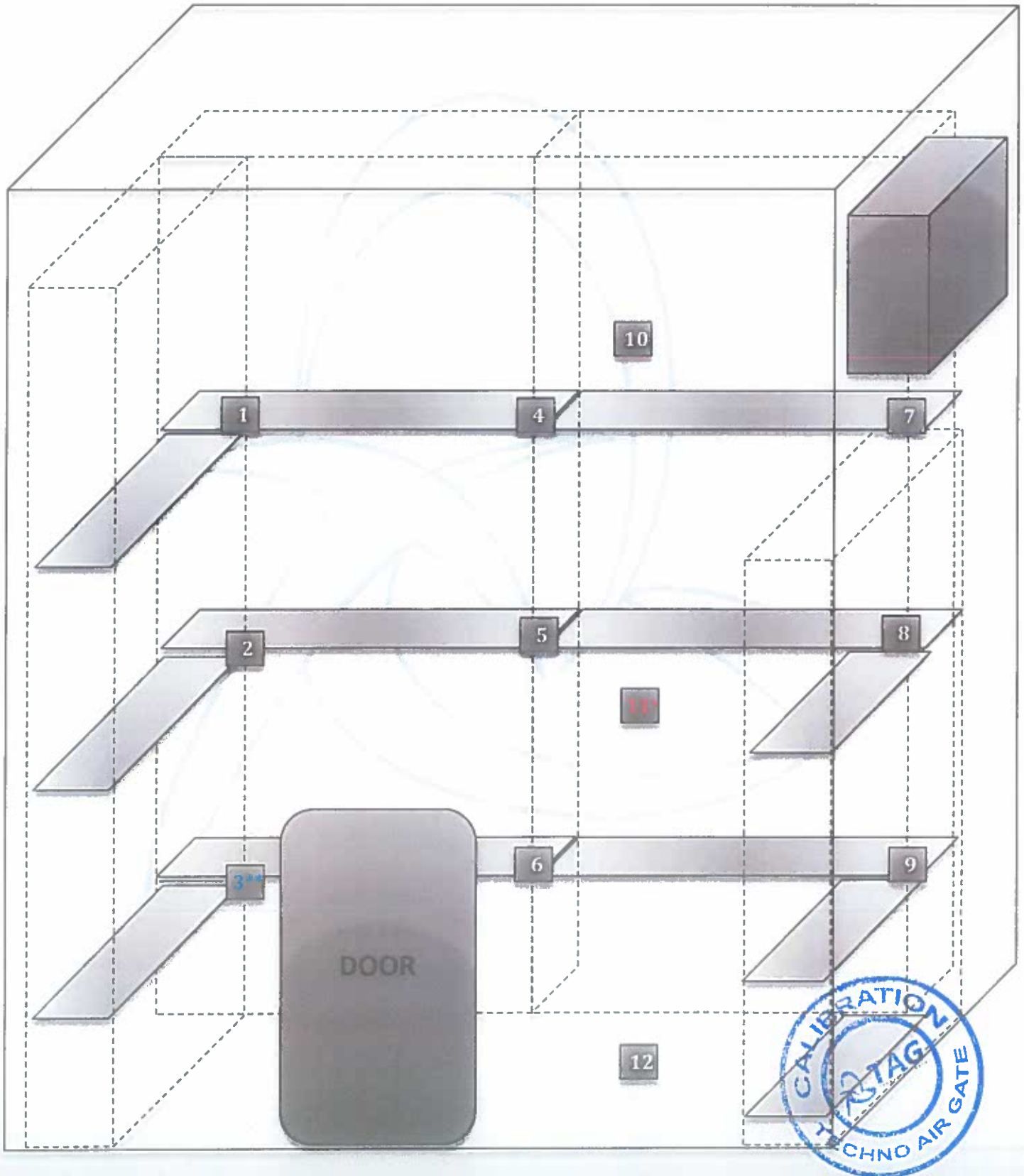
Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 11 of 19

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



*: Hot Spot.
**: Cold Spot.



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 12 of 19

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





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 13 of 19

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.03

DEVIATION REPORT



COLD ROOM PERFORMANCE QUALIFICATION



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 14 of 19

Datasheet Number 01.01.02.01: Deviation Report

DEVIATION REPORT

Copy 01 of 01

Test Report (N°. and Description):

Deviation N°:

Description:

Signature TAG:

Date:

Signature DR REDA PHARMACY STORE:

Date:

Corrective Action:

Person in charge to close the deviation

Expected closure date:

Signature TAG:

Date:

Signature QA DR REDA PHARMACY STORE:

Date:

Corrective Action results

Signature DR REDA PHARMACY STORE:

Date:

Deviation successfully solved? YES _____

NO _____

Signature:

Date:

Signature:

Date:



C O L D R O O M P E R F O R M A N C E Q U A L I F I C A T I O N



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 15 of 19

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.04

EQUIPMENT CALIBRATION VERIFICATION





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 16 of 19

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	1010148405	Apr., 2025	Oct., 2025
2.	Data Logger	LOG TAG /HAXO-08	1010161123	Apr., 2025	Oct., 2025
3.	Data Logger	LOG TAG /HAXO-08	1010148434	Apr., 2025	Oct., 2025
4.	Data Logger	LOG TAG /HAXO-08	1010148403	Apr., 2025	Oct., 2025
5.	Data Logger	LOG TAG /HAXO-08	1010157753	Apr., 2025	Oct., 2025
6.	Data Logger	LOG TAG /HAXO-08	1010149993	Apr., 2025	Oct., 2025
7.	Data Logger	LOG TAG /HAXO-08	1010149815	Apr., 2025	Oct., 2025
8.	Data Logger	LOG TAG /HAXO-08	1010148421	Apr., 2025	Oct., 2025
9.	Data Logger	LOG TAG /HAXO-08	1010157757	Apr., 2025	Oct., 2025
10.	Data Logger	LOG TAG /HAXO-08	1010148440	Apr., 2025	Oct., 2025
11.	Data Logger	LOG TAG /HAXO-08	1010161113	Apr., 2025	Oct., 2025
12.	Data Logger	LOG TAG /HAXO-08	1010148407	Apr., 2025	Oct., 2025

Reviewed By (TAG)

Reviewed By (DR REDA PHARMACY STORE)

Name

Ahmed Tarek

Signature

Date

30-06-2025





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 17 of 19

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.05

LIST OF ATTACHEMENTS





Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 18 of 19

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	Raw Data (on CD)	Annex-01.02 (Turn Over Package)
01.02.01.03	Inspection Label	Annex-01.02 (Turn Over Package)
01.02.01.04	Reference Equipment Calibration Certificates	Annex-01.02 (Turn Over Package)
01.02.01.05	Inspection Certificate	Annex-01.02 (Turn Over Package)

Reviewed By (TAG)

Reviewed By (DR REDA PHARMACY STORE)

Name

Ahmed Tarek

Signature

Date

30-06-2025



COLD ROOM PERFORMANCE QUALIFICATION



Vol 01) Annex 01.01)
Results Data Sheets
COLD ROOM



Jul., 2025

Rev. No.: 00

Doc. No.: PQR-M-00725

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

Page 19 of 19

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>Bassant Waleed</u> Name	<u>Bassant</u> Signature	<u>T.O.E</u> Title	<u>TAG</u> Company	<u>30-06-2025</u> Date
Approved by	<u>Abdelrahman Ramadan</u> Name	<u>A. Ramadan</u> Signature	<u>P.E.</u> Title	<u>TAG</u> Company	<u>30-06-2025</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>30-06-2025</u> Date
Approved by	<u>Ahmed Tarek</u> Name	<u>Ahmed Tarek</u> Signature	<u>T.M.</u> Title	<u>TAG</u> Company	<u>30-06-2025</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

