



VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

OVEN

(M-EQP-OV002)

OF

MIDDLE EAST FOR VACCINES (MEVAC)

AL-SALEHIA

CLIENT:



QUALIFICATION PROVIDER:



Package Content:

VOL-01 Performance Qualification Protocol

Annex-01.01) Results Data Sheets

Annex-01.02) Turn Over Package (Attachments)



Table of Content

Page

1. REPORT REVIEW AND APPROVAL	3
2. INTRODUCCION	4
2.1. Report Purpose	4
2.2. System Brief Description	4
2.3. Associated Material and Equipment Description	4
2.4. Study Design	5
3. RESULTS DATA SHEETS	6
DATA SHEET (01.01.01) MAIN CYCLES TEST RESULTS	6
01.01.01.01) EMPTY CYCLE TEST RESULTS	7
01.01.01.01.01) Empty Cycle Test Results Data Sheets	8
01.01.01.01.02) Empty Cycle Conclusion and Recommendation	9
01.01.01.01.03) Empty Cycle Layout and Sensors' Distribution	10
01.01.01.01.04) Empty Cycle Live Photos	11
01.01.01.02) Maximum Load penetration CYCLE TEST RESULTS	12
01.01.01.02.01) Maximum Load penetration Cycle Test Results Data Sheets	13
01.01.01.02.02) Maximum Load penetration Cycle Conclusion and Recommendation	14
01.01.01.02.03) Maximum Load penetration Cycle Layout and Sensors' Distribution	15
01.01.01.02.04) Maximum Load penetration Cycle Live Photos	16
DATA SHEET (01.01.02) DEVIATION REPORT	17
01.01.02.01) Deviation Report	13
DATA SHEET (01.01.03) REFERENCE EQUIPMENT LIST AND CALIBRATION VERIFICATION	19
01.01.03.01) Reference Equipment List	15
01.01.03.02) Sensors Pre-Calibration Check	16
01.01.03.03) Sensors Post-Calibration Check	17
DATA SHEET (01.01.04) LIST OF ATTACHEMENTS	24
01.01.04.01) List of Attachments	19
Final Review And Approval	25

1. REPORT REVIEW AND APPROVAL

TAG Author(s)

Name	Title	Company	Date	Signature
Salma Salah	T.O.E.	TAG	29/05/2025	

TAG Inspector(s)

Name	Title	Company	Date	Signature
Ahmed Mohamed	P.E.	TAG	29/05/2025	

TAG Reviewers(s)

Name	Title	Company	Date	Signature
Noha Essam	SR. T.O.E	TAG	29/05/2025	

TAG Approver(s)

Name	Title	Company	Date	Signature
Ahmed Tarek	T.M.	TAG	29/05/2025	

MIDDLE EAST FOR VACCINES (MEVAC) Reviewer(s)

Name	Title	Company	Date	Signature

MIDDLE EAST FOR VACCINES (MEVAC) Approver(s)

Name	Title	Company	Date	Signature

Change History

No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	29/05/2025

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 heat distribution within the Oven located at MIDDLE EAST FOR VACCINES (MEVAC). 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.
 -  FH-value for each location.
 -  Average temperature across all locations.
- 2.1.2 Identifying the hottest and coolest points and illustrating their locations on the layout diagram.
- 2.1.3 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.

2.2. System Brief Description

The scope of this report intends to cover the performance qualification results of Oven (M-EQP-OV002) located at MIDDLE EAST FOR VACCINES (MEVAC) with the following description:

System Brief Description	
Description	Oven
Dimensions/Volume	--
Manufacturing	BINDER
Model	FED400
S.N.	10-18626
Code	M-EQP-OV002
Location	Washing B1.2.240

2.3. Associated Material and Equipment Description

Used Reference Equipment Description						
Description	No. of sensors	Range	Accuracy	Manufacturer	Model	Calibration Due Date
Thermocouples	10 sensors	Multi-con	± 0.5 °C	Tecnosoft s.r.l.	CMC-N16	Oct., 2025

2.4. Study Design

Heat Distribution Study Design					
Sterilization Temp. Setting			@ 200 °C		
Accepted Sterilization Temp.			(200 ± 20) °C		
Sterilization Time Setting			For 2 hrs		
Accepted Sterilization Time			NLT 2 hrs		
Cycle No.	Cycle Description	Load Description	Start Date	Stop Date	Sample Frequency
1.	Empty	No Load	27/05/2025 02:25:07 PM	27/05/2025 04:25:07 PM	15 seconds
2.	Max. Load Penetration	10 Bottles 2000 m	27/05/2025 06:38:07 PM	27/05/2025 08:38:07 PM	15 seconds

3. RESULTS DATA SHEETS

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01

MAIN CYCLES TEST RESULTS

Content:

01.01.01.01 Empty Cycle Test Results

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01.01

EMPTY CYCLE TEST RESULTS

May 2025

Rev. No.: 00

Doc. No.: PQR-V-00525

F-7.4/34
Issue Date: 02/02/2025

Page 8 of 25

Datasheet number 01.01.01.01.01: Empty Cycle Test Results Data Sheets

Heat Distribution Study Data Sheet for Oven (M-EQP-OV002)					
Cycle No.	1 of 2				
Cycle Name	Empty Cycle				
Load Description	No Load				
Sterilization Temp. Setting	@ 200 °C				
Accepted Sterilization Temp.	(200 ± 20) °C				
Sterilization Time Setting	for 2 hrs.				
Accepted Sterilization Time	NLT 2 hrs.				
Cycle Start Time	27/05/2025 02:25:07 PM	Cycle End Time	27/05/2025 04:25:07 PM		
Sterilization Start Time	27/05/2025 02:25:07 PM	Sterilization End Time	27/05/2025 04:25:07 PM		
Sensor Position	Sensor S/N	Actual			Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum	
		Temp. (°C)	T (°C)	T (°C)	
1.	Inp. C2 [°C] (20)	193.6**	195.6	181.9	YES
2.	Inp. B7 [°C] (16)	199.6	201.4	190.6	YES
3.	Inp. C3 [°C] (21)	201.4	203.9	192.1	YES
4.	Inp. A5 [°C] (5)	195.8	197.6	182.2	YES
5.	Inp. B4 [°C] (13)	194.6	196.6	185.9	YES
6.	Inp. C1 [°C] (19)	193.9	195.8	181.3	YES
7.	Inp. B6 [°C] (15)	201.0	203.4	190.8	YES
8.	Inp. A8 [°C] (8)	205.6*	207.5*	197.5	YES
9.	Inp. B5 [°C] (14)	194.0	195.8	180.2**	YES
10.	Inp. B3 [°C] (12)	202.4	205.1	187.8	YES
Average for Oven		198.2			

*: Maximum & Hottest.

**: Minimum & Coolest.

NOTES:

OVEN PERFORMANCE QUALIFICATION

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

Ahmed Tarek

Signature

Date

29/05/2025

Datasheet number 01.01.01.01.02: Empty Cycle Final Report and Conclusion

- All the registered charts, graphs, and raw data (CD) are attached in the TOP.
- The following table presents a summary of the monitored data all over the sterilization period. All obtained values are not rounded.

Results Summary			
Parameter	Value	Location No.	Sensor S.N.
Min. Sterilization Temp.	180.2 °C	9	Inp. B5 [°C] (14)
Max. Sterilization Temp.	207.5 °C	8	Inp. A8 [°C] (8)
Hottest Point Temperature	205.6 °C	8	Inp. A8 [°C] (8)
Coollest Point Temperature	193.6 °C	1	Inp. C2 [°C] (20)
Holding Time (Exposure Time)	2 hrs.		

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

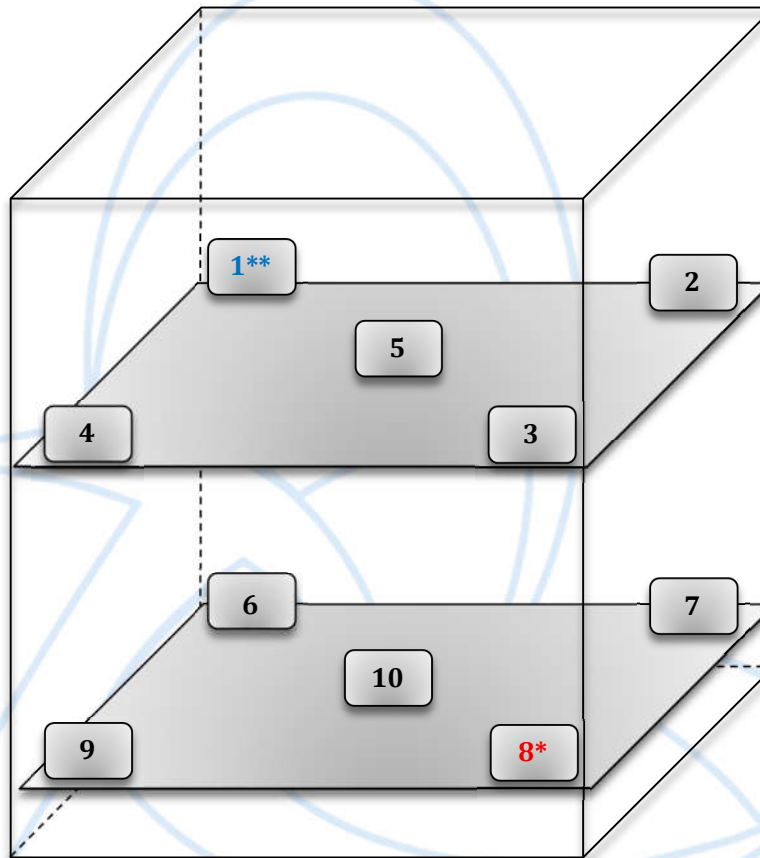
Ahmed Tarek

Signature

Date

29/05/2025

Datasheet number 01.01.01.01.03: Empty Cycle Layout and Sensors' Distribution



*: Hottest.
*: Coolest.

Datasheet number 01.01.01.01.04: Empty Cycle Live Photos



VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01.02

Maximum Load Penetration CYCLE TEST
RESULTS

May 2025

Rev. No.: 00

Doc. No.: PQR-V-00525

F-7.4/34
Issue Date: 02/02/2025

Page 13 of 25

Datasheet number 01.01.01.02.01: Maximum Load Penetration Cycle Test Results Data Sheets

Heat Distribution Study Data Sheet for Oven (M-EQP-OV002)					
Cycle No.	2 of 2				
Cycle Name	Maximum Load Penetration Cycle				
Load Description	10 Bottles 2000 m				
Sterilization Temp. Setting	@ 200 °C				
Accepted Sterilization Temp.	(200 ± 20) °C				
Sterilization Time Setting	for 2 hrs.				
Accepted Sterilization Time	NLT 2 hrs.				
Cycle Start Time	27/05/2025 04:38:07 PM	Cycle End Time	27/05/2025 06:38:07 PM		
Sterilization Start Time	27/05/2025 04:38:07 PM	Sterilization End Time	27/05/2025 06:38:07 PM		
Sensor Position	Sensor S/N	Actual			Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum	
		Temp. (°C)	T (°C)	T (°C)	
1.	Inp. C2 [°C] (20)	191.4**	192.6	181.9	YES
2.	Inp. B7 [°C] (16)	200.7	201.5	192.6	YES
3.	Inp. C3 [°C] (21)	204.1	204.8	198.0	YES
4.	Inp. A5 [°C] (5)	193.5	194.7	183.4	YES
5.	Inp. B4 [°C] (13)	194.6	195.5	186.3	YES
6.	Inp. C1 [°C] (19)	191.7	193.3	180.0**	YES
7.	Inp. B6 [°C] (15)	200.5	201.5	191.1	YES
8.	Inp. A8 [°C] (8)	207.7*	208.4*	201.2	YES
9.	Inp. B5 [°C] (14)	192.3	193.3	182.9	YES
10.	Inp. B3 [°C] (12)	198.4	199.9	184.3	YES
Average for Oven		197.5			

*: Maximum & Hottest.

**: Minimum & Coolest.

NOTES:

OVEN PERFORMANCE QUALIFICATION

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

Ahmed Tarek

Signature

Date

29/05/2025

Datasheet number 01.01.01.02.02: Maximum Load Penetration Cycle Final Report and Conclusion

- All the registered charts, graphs, and raw data (CD) are attached in the TOP.
- The following table presents a summary of the monitored data all over the sterilization period. All obtained values are not rounded.

Results Summary			
Parameter	Value	Location No.	Sensor S.N.
Min. Sterilization Temp.	180.0 °C	6	Inp. C1 [°C] (19)
Max. Sterilization Temp.	208.4 °C	8	Inp. A8 [°C] (8)
Hottest Point Temperature	207.7 °C	8	Inp. A8 [°C] (8)
Coollest Point Temperature	191.4 °C	1	Inp. C2 [°C] (20)
Holding Time (Exposure Time)	2 hrs.		

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

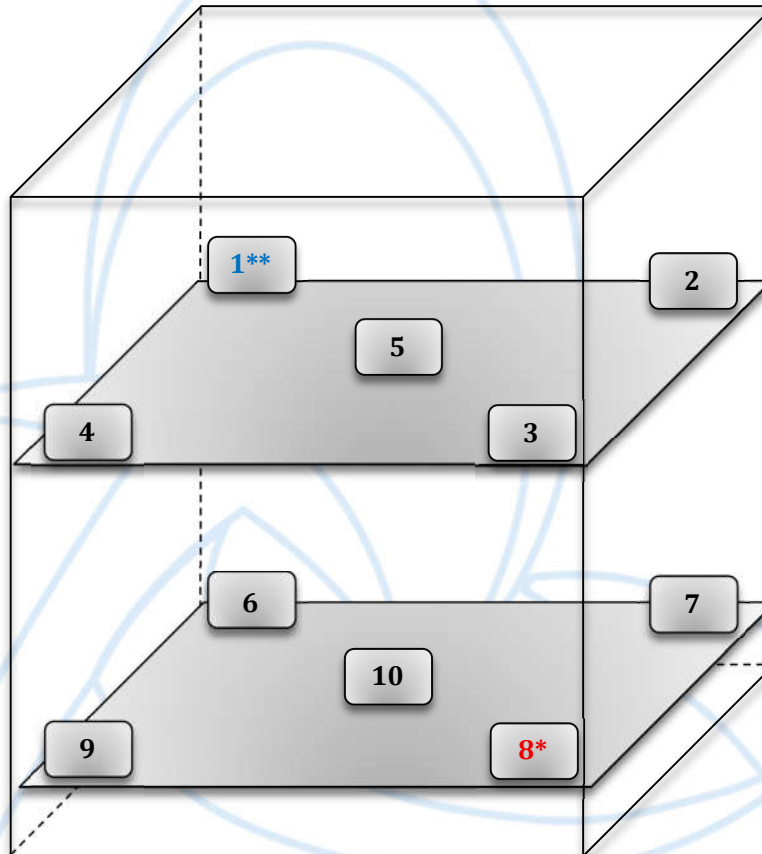
Ahmed Tarek

Signature

Date

29/05/2025

Datasheet number 01.01.01.02.03: Maximum Load Penetration Cycle Layout and Sensors' Distribution



*: Hottest.
**: Coolest.

Datasheet number 01.01.01.02.04: Maximum Load Penetration Cycle Live Photos



VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.02

DEVIATION REPORT

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 MIDDLE EAST FOR VACCINES (MEVAC) :		Date:
Corrective Action:		
Person in charge to close the deviation		Expected closure date:
Signature TAG :		Date:
Signature QA MIDDLE EAST FOR VACCINES (MEVAC) :		Date:
Corrective Action results		
Signature MIDDLE EAST FOR VACCINES (MEVAC) :		Date:
Deviation successfully solved? YES_____		NO_____
Signature:		Date:
Signature:		Date:

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.03

REFERENCE EQUIPMENT LIST AND
CALIBRATION VERIFICATION

Datasheet Number 01.01.03.01: Reference Equipment List

Reference Equipment List					
Instrument Description				CALIBRATION	
No.	Instrument Description	Manufacturer/ Model	S.N.	Most recent calibration date	Calibration Due Date
1.	Thermocouple	Multi-con/CMC-N16	Inp. C2 [°C] (20)	Apr., 2025	Oct., 2025
2.	Thermocouple	Multi-con/CMC-N16	Inp. B7 [°C] (16)	Apr., 2025	Oct., 2025
3.	Thermocouple	Multi-con/CMC-N16	Inp. C3 [°C] (21)	Apr., 2025	Oct., 2025
4.	Thermocouple	Multi-con/CMC-N16	Inp. A5 [°C] (5)	Apr., 2025	Oct., 2025
5.	Thermocouple	Multi-con/CMC-N16	Inp. B4 [°C] (13)	Apr., 2025	Oct., 2025
6.	Thermocouple	Multi-con/CMC-N16	Inp. C1 [°C] (19)	Apr., 2025	Oct., 2025
7.	Thermocouple	Multi-con/CMC-N16	Inp. B6 [°C] (15)	Apr., 2025	Oct., 2025
8.	Thermocouple	Multi-con/CMC-N16	Inp. A8 [°C] (8)	Apr., 2025	Oct., 2025
9.	Thermocouple	Multi-con/CMC-N16	Inp. B5 [°C] (14)	Apr., 2025	Oct., 2025
10.	Thermocouple	Multi-con/CMC-N16	Inp. B3 [°C] (12)	Apr., 2025	Oct., 2025

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

Ahmed Tarek

Signature

Date

29/05/2025

Datasheet Number 01.01.03.02: Sensors Pre-Calibration Check

Reference Equipment List					
Equipment Description	Manufacturer	Model	S.N.	Most recent calibration date	Calibration Due Date
Pt-100 with digital indicator	GREISINGER	GMH 3710	32403245/116	Mar., 2025	Mar., 2026

Pre-Calibration Check Results				
No.	Sensors S.N.	Error @ 180 °C	Error @ 200 °C	Error @ 220 °C
		(°C)	(°C)	(°C)
1.	Inp. C2 [°C] (20)	0.1	-0.2	-0.5
2.	Inp. B7 [°C] (16)	-0.1	-0.3	-0.4
3.	Inp. C3 [°C] (21)	-0.1	-0.3	-0.5
4.	Inp. A5 [°C] (5)	-0.1	-0.3	-0.5
5.	Inp. B4 [°C] (13)	0.1	0.0	-0.1
6.	Inp. C1 [°C] (19)	0.3	0.2	0.0
7.	Inp. B6 [°C] (15)	-0.4	-0.5	-0.5
8.	Inp. A8 [°C] (8)	-0.1	-0.3	-0.4
9.	Inp. B5 [°C] (14)	-0.1	-0.3	-0.5
10.	Inp. B3 [°C] (12)	0.0	-0.2	-0.3

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

Ahmed Tarek

Signature

Date

29/05/2025

Datasheet Number 01.01.03.03: Sensors Post-Calibration Check

Reference Equipment List					
Equipment Description	Manufacturer	Model	S.N.	Most recent calibration date	Calibration Due Date
Pt-100 with digital indicator	GREISINGER	GMH 3710	32403245/116	Mar., 2025	Mar., 2026

Post-Calibration Check Results				
No.	Sensors S.N.	Error @ 170 °C	Error @ 185 °C	Error @ 200 °C
		(°C)	(°C)	(°C)
1.	Inp. C2 [°C] (20)	0.2	-0.2	-0.6
2.	Inp. B7 [°C] (16)	-0.1	-0.3	-0.5
3.	Inp. C3 [°C] (21)	-0.2	-0.3	-0.4
4.	Inp. A5 [°C] (5)	-0.2	-0.3	-0.3
5.	Inp. B4 [°C] (13)	0.3	0.0	-0.3
6.	Inp. C1 [°C] (19)	0.2	0.2	0.1
7.	Inp. B6 [°C] (15)	-0.3	-0.4	-0.4
8.	Inp. A8 [°C] (8)	-0.2	-0.4	-0.5
9.	Inp. B5 [°C] (14)	-0.1	-0.3	-0.4
10.	Inp. B3 [°C] (12)	0.2	0.0	-0.2

Reviewed By (TAG)

Reviewed By (MEVAC)

Name

Ahmed Tarek

Signature

Date

29/05/2025

VOL-01) PERFORMANCE QUALIFICATION PROTOCOL

ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.04

LIST OF ATTACHEMENTS

Datasheet Number 01.01.04.01: List of Attachments

List of Attachments		
Attachment No.	Description	Location
01.02.01.01	Empty Cycle Printouts	Annex-01.02 (Turn Over Package)
01.02.02.01	Maximum Load Penetration 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 (MEVAC)

Name

Ahmed Tarek

Signature

Date

29/05/2025

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		T.O.E.	TAG	
	Name	Signature	Title	Company	Date
Approved by	Ahmed Mohamed		P.E.	TAG	
	Name	Signature	Title	Company	Date
Approved by	Noha Essam		SR. T.O.E	TAG	
	Name	Signature	Title	Company	Date
Approved by	Ahmed Tarek		T.M.	TAG	
	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