



VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

OVEN

(MI-131)

OF

JAMJOOM PHARMA

EL-OBOUR 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	22/06/2025

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 heat distribution within the Oven located at **JAMJOOM PHARMA**. 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 (MI-131) located at **JAMJOOM PHARMA** with the following description:

System Brief Description	
Description	Oven
Dimensions/Volume	170 (L) / 6.1 (cuft)
Manufacturing	Thermo Scientific™
Model	Heratherm OMH180
S.N.	42914631
Code	MI-131
Location	Microbiology Laboratory

2.3. Associated Material and Equipment Description

Used Reference Equipment Description						
Description	No. of sensors	Range	Accuracy	Manufacturer	Model	Calibration Due Date
Thermocouples	12 sensors	Multi-con	± 0.5 °C	Tecnosoft s.r.l.	CMC-N16	Oct. 2025



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2.4. Study Design
Heat Distribution Study Design

Sterilization Temp. Setting		@ 185 °C			
Accepted Sterilization Temp.		(185 ± 5) °C			
Sterilization Time Setting		for 30 min			
Accepted Sterilization Time		NLT 30 min			
Cycle No.	Cycle Description	Load Description	Start Date	Stop Date	Sample Frequency
1.	Empty	No Load	18/06/2025 01:23:00 PM	18/06/2025 03:07:46 PM	15 seconds



3. RESULTS DATA SHEETS

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ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01

MAIN CYCLES TEST RESULTS

Content:

01.01.01.01 Empty Cycle Test Results



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ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01.01

EMPTY CYCLE TEST RESULTS



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Datasheet number 01.01.01.01.01: Empty Cycle Test Results Data Sheets
Heat Distribution Study Data Sheet for Oven (MI-131)

Cycle No.	1 of 5					
Cycle Name	Empty Cycle					
Load Description	No Load					
Sterilization Temp. Setting	@ 185 °C					
Accepted Sterilization Temp.	(185 ± 5) °C					
Sterilization Time Setting	for 30 min					
Accepted Sterilization Time	NLT 30 min					
Cycle Start Time	18/06/2025 01:23:00 PM	Cycle End Time	18/06/2025 03:07:46 PM			
Sterilization Start Time	18/06/2025 02:00:16 PM	Sterilization End Time	18/06/2025 02:36:31 PM			
Sensor Position	Sensor S/N	Actual			F ₀ value	Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum		
		Temp. [°C]	T [°C]	T [°C]		
1.	Inp. A1 [°C] (1)	183.60	183.80	183.40	112.06	YES
2.	Inp. A2 [°C] (2)	182.25	182.50	181.80	95.35	YES
3.	Inp. A3 [°C] (3)	183.04	183.20	182.90	105.04	YES
4.	Inp. A4 [°C] (4)	184.51*	184.70*	184.20	123.66	YES
5.	Inp. A5 [°C] (5)	183.40	183.50	183.20	109.56	YES
6.	Inp. A6 [°C] (6)	180.27**	180.50	180.00**	76.01	YES
7.	Inp. A7 [°C] (7)	183.46	183.60	183.00	110.34	YES
8.	Inp. B1 [°C] (10)	183.80	183.90	183.20	114.92	YES
9.	Inp. B8 [°C] (17)	182.90	183.10	181.90	103.39	YES
10.	Inp. B6 [°C] (15)	182.98	183.10	181.80	104.49	YES
11.	Inp. B2 [°C] (11)	183.34	183.50	182.40	108.97	YES
12.	Inp. B7 [°C] (16)	183.06	183.20	182.20	105.33	YES
Average for Oven		183.05				

*: Maximum & Hottest.

**: Minimum & Coolest.

NOTES:

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

Signature



Date

22/06/2025



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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.	180.00 °C	6	Inp. A6 [°C] (6)
Max. Sterilization Temp.	184.70 °C	4	Inp. A4 [°C] (4)
Hottest Point Temperature	184.51 °C	4	Inp. A4 [°C] (4)
Coollest Point Temperature	180.27 °C	6	Inp. A6 [°C] (6)
Minimum F _H -value	76.01 °C	6	Inp. A6 [°C] (6)
Holding Time (Exposure Time)	36 min & 15 sec		

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

Signature

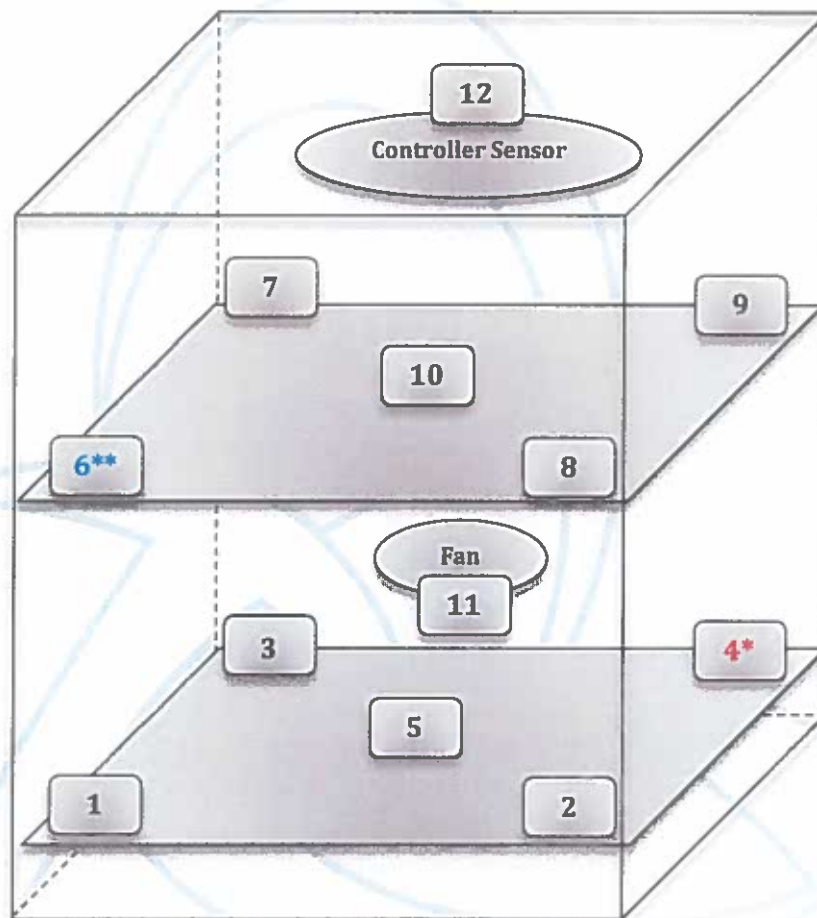


Date

22/06/2025



Datasheet number 01.01.01.01.03: Empty Cycle Layout and Sensors' Distribution



*: Hottest.

** : Coolest.



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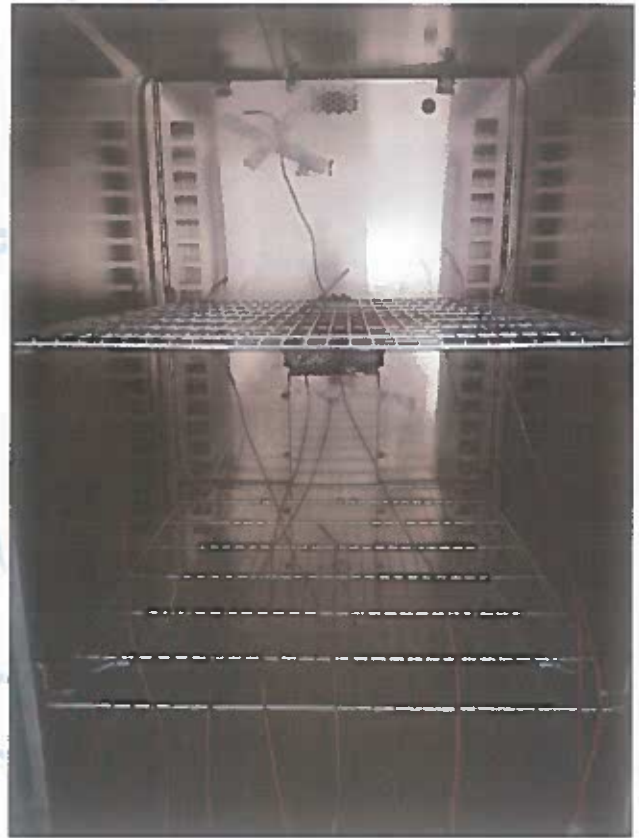
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Datasheet number 01.01.01.01.04: Empty Cycle Live Photos



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RESULTS DATA SHEETS

DATA SHEET 01.01.02

DEVIATION REPORT



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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 JAMJOOM PHARMA:	Date:	
Corrective Action:		
Person in charge to close the deviation	Expected closure date:	
Signature TAG:	Date:	
Signature QA JAMJOOM PHARMA:	Date:	
Corrective Action results		
Signature JAMJOOM PHARMA:	Date:	
Deviation successfully solved? YES _____	NO _____	
Signature:	Date:	
Signature:	Date:	



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RESULTS DATA SHEETS

DATA SHEET 01.01.03

**REFERENCE EQUIPMENT LIST AND
CALIBRATION VERIFICATION**



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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. A1 [°C] (1)	Apr., 2025	Oct., 2025
2.	Thermocouple	Multi-con/CMC-N16	Inp. A2 [°C] (2)	Apr., 2025	Oct., 2025
3.	Thermocouple	Multi-con/CMC-N16	Inp. A3 [°C] (3)	Apr., 2025	Oct., 2025
4.	Thermocouple	Multi-con/CMC-N16	Inp. A4 [°C] (4)	Apr., 2025	Oct., 2025
5.	Thermocouple	Multi-con/CMC-N16	Inp. A5 [°C] (5)	Apr., 2025	Oct., 2025
6.	Thermocouple	Multi-con/CMC-N16	Inp. A6 [°C] (6)	Apr., 2025	Oct., 2025
7.	Thermocouple	Multi-con/CMC-N16	Inp. A7 [°C] (7)	Apr., 2025	Oct., 2025
8.	Thermocouple	Multi-con/CMC-N16	Inp. B1 [°C] (10)	Apr., 2025	Oct., 2025
9.	Thermocouple	Multi-con/CMC-N16	Inp. B8 [°C] (17)	Apr., 2025	Oct., 2025
10.	Thermocouple	Multi-con/CMC-N16	Inp. B6 [°C] (15)	Apr., 2025	Oct., 2025
11.	Thermocouple	Multi-con/CMC-N16	Inp. B2 [°C] (11)	Apr., 2025	Oct., 2025
12.	Thermocouple	Multi-con/CMC-N16	Inp. B7 [°C] (16)	Apr., 2025	Oct., 2025

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

Signature

Date

22/06/2025



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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 @ 170 °C	Error @ 185 °C	Error @ 200 °C
		(°C)	(°C)	(°C)
1.	Inp. A1 [°C] (1)	0.1	-0.2	-0.5
2.	Inp. A2 [°C] (2)	-0.1	-0.3	-0.4
3.	Inp. A3 [°C] (3)	-0.1	-0.3	-0.5
4.	Inp. A4 [°C] (4)	-0.1	-0.3	-0.5
5.	Inp. A5 [°C] (5)	0.1	0.0	-0.1
6.	Inp. A6 [°C] (6)	0.3	0.2	0.0
7.	Inp. A7 [°C] (7)	-0.4	-0.5	-0.5
8.	Inp. B1 [°C] (10)	-0.1	-0.3	-0.4
9.	Inp. B8 [°C] (17)	-0.1	-0.3	-0.5
10.	Inp. B6 [°C] (15)	0.0	-0.2	-0.3
11.	Inp. B2 [°C] (11)	0.0	-0.3	-0.5
12.	Inp. B7 [°C] (16)	0.1	-0.1	-0.3

Reviewed By (TAG)
Reviewed By (JAMJOOM PHARMA)
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Date
22/06/2025


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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. A1 [°C] (1)	0.2	-0.2	-0.6
2.	Inp. A2 [°C] (2)	-0.1	-0.3	-0.5
3.	Inp. A3 [°C] (3)	-0.2	-0.3	-0.4
4.	Inp. A4 [°C] (4)	-0.2	-0.3	-0.3
5.	Inp. A5 [°C] (5)	0.3	0.0	-0.3
6.	Inp. A6 [°C] (6)	0.2	0.2	0.1
7.	Inp. A7 [°C] (7)	-0.3	-0.4	-0.4
8.	Inp. B1 [°C] (10)	-0.2	-0.4	-0.5
9.	Inp. B8 [°C] (17)	-0.1	-0.3	-0.4
10.	Inp. B6 [°C] (15)	0.2	0.0	-0.2
11.	Inp. B2 [°C] (11)	0.1	-0.1	-0.3
12.	Inp. B7 [°C] (16)	0.2	-0.1	-0.4

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

Signature



Date

22/06/2025



VOL-01) PERFORMANCE QUALIFICATION PROTOCOL**ANNEX 01.01****RESULTS DATA SHEETS****DATA SHEET 01.01.04****LIST OF ATTACHEMENTS**

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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)
01.02.01.02	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 (JAMJOOM PHARMA)

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Date 22/06/2025



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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	<u>Shimaa Badr</u>	<u>Shimaa</u>	<u>T.O.E.</u>	<u>TAG</u>	<u>22-06-2025</u>
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	Name	Signature	Title	Company	Date

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	Name	Signature	Title	Company	Date

Approved by	<u>Ahmed Tarek</u>	<u>Ahmed</u>	<u>T.M.</u>	<u>TAG</u>	<u>22-06-2025</u>
	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

