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VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR
AUTOCLAVE
(MI-193)
OF
JAMJOOM PHARMA
EL-BOUR 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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JAMJOOM PHARMA Approver(s)

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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 Autoclave 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.
- ⌚ F₀-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 Autoclave (MI-193) located at JAMJOOM PHARMA with the following description:

System Brief Description	
Description	Autoclave
Dimensions/Volume	690 L
Manufacturing	Fedegari
Model	FOB5S-TS
S.N.	NBI901BC
Code	MI-193
Location	Microbiology Laboratory, Preparation Room MC-22

2.3. Associated Material and Equipment Description

Used Reference Equipment Description						
Description	No. of sensors	Range	Accuracy	Manufacturer	Model	Calibration Due Date
Data Loggers	12 sensors	(-40) °C to (140) °C	± 0.5 °C	Tecnosoft s.r.l.	SterilDial Probe	Nov., 2025
Data Loggers	01 sensors	(0) bar to (4) bar	± 5% of F.S	Tecnosoft s.r.l.	Pressure Disk	Nov., 2025



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2.4. Study Design
Heat Distribution Study Design

Sterilization Temp. Setting	122 °C
Accepted Sterilization Temp.	(121 + 3) °C
Sterilization Time Setting	for 20 min
Accepted Sterilization Time	NLT 20 min
Accepted F₀-value	≥ 20 (as per customer requirement)

Cycle No.	Cycle Description	Load Description	Start Date	Stop Date	Sample Frequency
1.	Liquid	23.150 L 111 Flask 100ml 12 Flask 1000ml 1 Flask 250ml	18/06/2025 01:30:00 PM	18/06/2025 02:57:45 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 Liquid Cycle Test Results



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ANNEX 01.01

RESULTS DATA SHEETS

DATA SHEET 01.01.01.01

LIQUID CYCLE TEST RESULTS



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Datasheet number 01.01.01.01.01: Liquid Cycle Test Results Data Sheets

Heat Distribution Study Data Sheet for Autoclave (MI-193)						
Cycle No.	1 of 1					
Cycle Name	Liquid Cycle					
Load Description	23.150 L 111 Flask-100ml & 12 Flask-1000ml & 1 Flask-250ml					
Sterilization Temp. Setting	122 °C					
Accepted Sterilization Temp.	(121 + 3) °C					
Sterilization Time Setting	for 20 min					
Accepted Sterilization Time	NLT 20 min					
Accepted F ₀ -value	≥ 20 (as per customer requirement)					
Cycle Start Time	22/06/2025 01:30:00 PM	Cycle End Time	22/06/2025 02:57:45 PM			
Sterilization Start Time	22/06/2025 01:58:30 PM	Sterilization End Time	22/06/2025 02:21:45 PM			
Sensor Position	Sensor S/N	Actual			F ₀ -value	Within Acceptance Criteria (YES / NO)?
		Average Temp. (°C)	Maximum T (°C)	Minimum T (°C)		
1.	1011004509	123.02	123.17	122.47	31.50	YES
2.	1011000232	122.83	122.99	122.27	30.18	YES
3.	1011004093	123.00	123.10	122.67	31.35	YES
4.	1011004331	123.08	123.20	122.72	31.98	YES
5.	1011004211	122.69	122.80	122.43	29.23	YES
6.	1011004503	123.03	123.17	122.55	31.60	YES
7.	1011004106	123.06	123.18	122.61	31.83	YES
8.	1011004332	123.07	123.19	122.72	31.85	YES
9.	1011003860	123.10	123.21	122.82	32.08	YES
10.	1011004102	122.98	123.08	122.54	31.21	YES
11.	1011004404	122.35**	122.49	121.87**	27.02**	YES
12.	1011004203	123.15*	123.25*	123.04	32.45*	YES
13.	Pressure	2.267	2.274	2.26	--	--
Average for Autoclave		122.88				

*: Maximum & Hottest.

**: Minimum & Coolest.

NOTES:

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

Signature



Date

22/06/2025



Datasheet number 01.01.01.01.02: Liquid 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.	121.10 °C	11	1011004404
Max. Sterilization Temp.	123.26 °C	12	1011004203
Hottest Point Temperature	123.14 °C	12	1011004203
Coolest Point Temperature	122.26 °C	11	1011004404
Minimum F0-value	30.80	11	1011004404
Slowest Point		1011004404	
Equilibrium Time		5 min & 15 sec	
Holding Time (Exposure Time)		23 min & 15 sec	
Plateau Period		28 min & 30 sec	

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

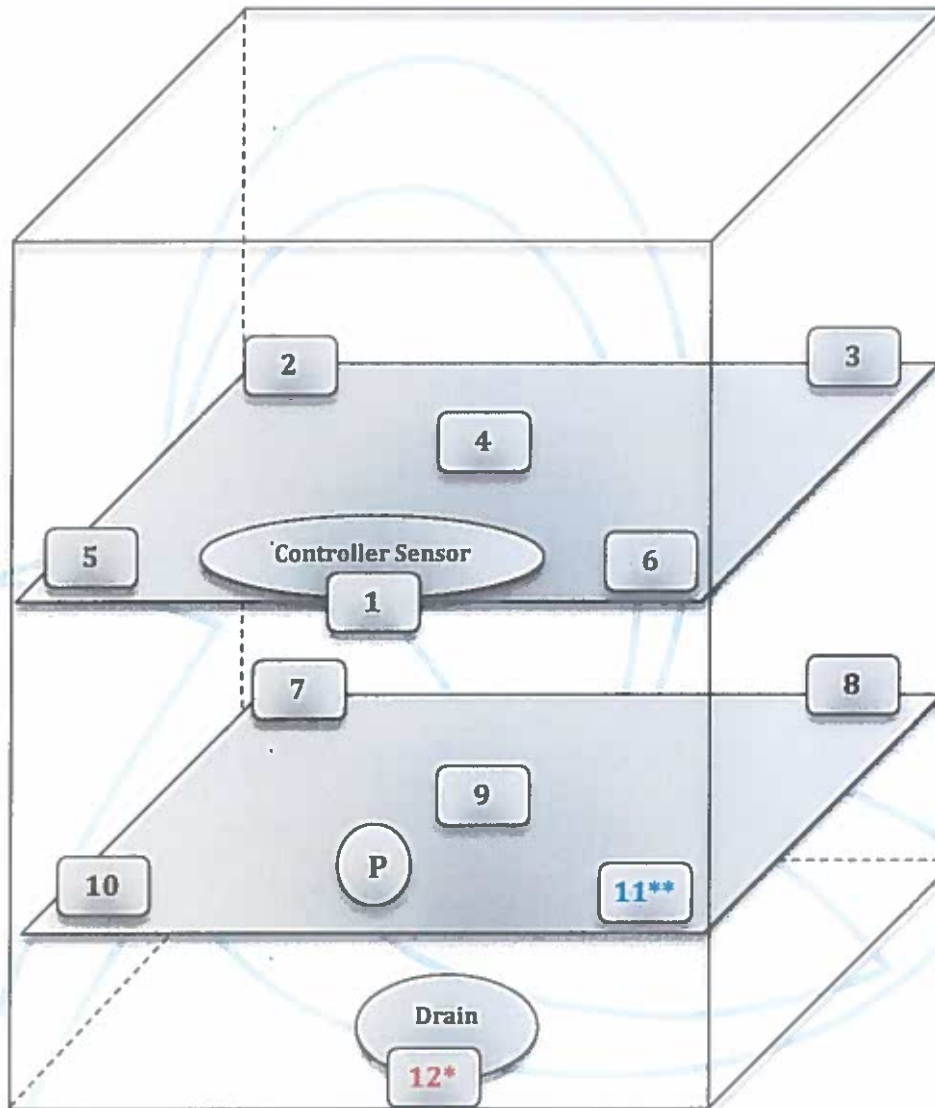
Signature

Date

22/06/2025



Datasheet number 01.01.01.01.03: Liquid Cycle Layout and Sensors' Distribution



*: Hottest.

** : Coolest.



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Datasheet number 01.01.01.01.04: Liquid Cycle Live Photos



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ANNEX 01.01
RESULTS DATA SHEETS

DATA SHEET 01.01.02
DEVIATION REPORT



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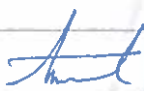
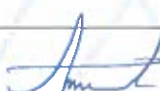
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Datasheet Number 01.01.02.01: Deviation Report

DEVIATION REPORT		Copy 01 of 01
Test Report (N°. and Description):	Deviation N°:	
Description: The equilibrium time was recorded as 5 minutes and 15 seconds, exceeding the specified limit of not more than 30 seconds. However, this result has been accepted by the customer.		
Signature TAG: 	Date: 22-06-2025	
Signature JAMJOOM PHARMA:	Date:	
Corrective Action:		
Person in charge to close the deviation	Expected closure date:	
Signature TAG: 	Date: 22-06-2025	
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.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004509	May., 2025	Nov., 2025
2.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011000232	May., 2025	Nov., 2025
3.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004093	May., 2025	Nov., 2025
4.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004331	May., 2025	Nov., 2025
5.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004211	May., 2025	Nov., 2025
6.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004503	May., 2025	Nov., 2025
7.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004106	May., 2025	Nov., 2025
8.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004332	May., 2025	Nov., 2025
9.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011003860	May., 2025	Nov., 2025
10.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004102	May., 2025	Nov., 2025
11.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004404	May., 2025	Nov., 2025
12.	Data Logger	Tecnosoftware s.r.l./ SterilDisk Probe	1011004203	May., 2025	Nov., 2025
13.	Data Logger	Tecnosoftware s.r.l./ PressureDisk 05	3501009327	May., 2025	Nov., 2025

Reviewed By (TAG)

Name

Ahmed Tarek

Signature



Date

22/06/2025

Reviewed By (JAMJOOM PHARMA)



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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 @ 100 °C	Error @ 121 °C	Error @ 130 °C
		(°C)	(°C)	(°C)
1.	1011004509	-0.08	0.11	0.07
2.	1011000232	0.13	0.26	0.22
3.	1011004093	0.19	0.13	0.05
4.	1011004331	0.39	0.19	0.22
5.	1011004211	0.46	0.48	0.43
6.	1011004503	-0.01	0.14	0.11
7.	1011004106	-0.04	0.14	0.09
8.	1011004332	0.45	0.24	0.29
9.	1011003860	0.03	0.16	0.27
10.	1011004102	0.15	0.26	0.20
11.	1011004404	0.04	0.44	0.38
12.	1011004203	0.34	0.20	0.19

Reviewed By (TAG)

Reviewed By (JAMJOOM PHARMA)

Name

Ahmed Tarek

Signature

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 @ 100 °C	Error @ 121 °C	Error @ 130 °C
		(°C)	(°C)	(°C)
1.	1011004509	-0.07	0.12	0.08
2.	1011000232	0.19	0.32	0.28
3.	1011004093	0.23	0.17	0.09
4.	1011004331	0.36	0.16	0.19
5.	1011004211	0.51	0.53	0.48
6.	1011004503	-0.05	0.10	0.07
7.	1011004106	-0.06	0.12	0.07
8.	1011004332	0.48	0.27	0.32
9.	1011003860	0.07	0.20	0.31
10.	1011004102	0.20	0.31	0.25
11.	1011004404	0.06	0.46	0.40
12.	1011004203	0.37	0.23	0.22

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Reviewed By (JAMJOOM PHARMA)


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	Liquid 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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Ahmed Tarek
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Date
22/06/2025


AUTOCLAVE 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	<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
Approved by	<u>Noha Essam</u>	<u>Noha Essam</u>	<u>SR. T.O.E.</u>	<u>TAG</u>	<u>22-06-2025</u>
	Name	Signature	Title	Company	Date
Approved by	<u>Ahmed Tarek</u>	<u>Ahmed Tarek</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



AUTOCALVE PERFORMANCE QUALIFICATION