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VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

FOR

AUTOCLAVE

(MI-193)

OF

JAMJOOM PHARMA

EL-OBOUR CITY

CLIENT:	QUALIFICATION PROVIDER:
جمجوم فارما Jamjoom Pharma	TAG TECHNO AIR GATE

Package Content

EGYPT: 26 Al Israa St., Lebanon Sq., Mohandseen, Giza, Egypt

KSA: 3321, Prince Mamdouh Bin Abdulaziz St., Al Sulaymaniyah, Riyadh, KSA

UAE: Sharjah Media City, Sharjah, UAE

www.technoairgate.com info@technoairgate.com

+201023310801

+966543728852

+971502013049

+20233034440

Table of Content

1. PROTOCOL REVIEW AND APPROVAL

- Prior to the initiation of qualification testing activities, this document will be issued, reviewed and approved by the appropriate personnel.
- The signatures below signify prior approval of the format and content of the final report, ensuring an accurate representation of the qualification activities planned for JAMJOOM PHARMA.

TAG Author(s)

Name	Title	Company	Date	Signature
Shimaa Badr	T.O.E.	TAG	10/06/2025	Shaimaa

TAG Inspector(s)

Name	Title	Company	Date	Signature
Mahmoud Makhlouf	P.E.	TAG	10/06/2025	M. Makhlouf

TAG Reviewers(s)

Name	Title	Company	Date	Signature
Noha Essam	SR. T.O.E	TAG	10/06/2025	Noha Essam

TAG Approver(s)

Name	Title	Company	Date	Signature
Ahmed Tarek	T.M.	TAG	10/06/2025	

JAMJOOM PHARMA Reviewer(s)

Name	Title	Company	Date	Signature

JAMJOOM PHARMA Approver(s)

Name	Title	Company	Date	Signature

Change History

No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	10/06/2025

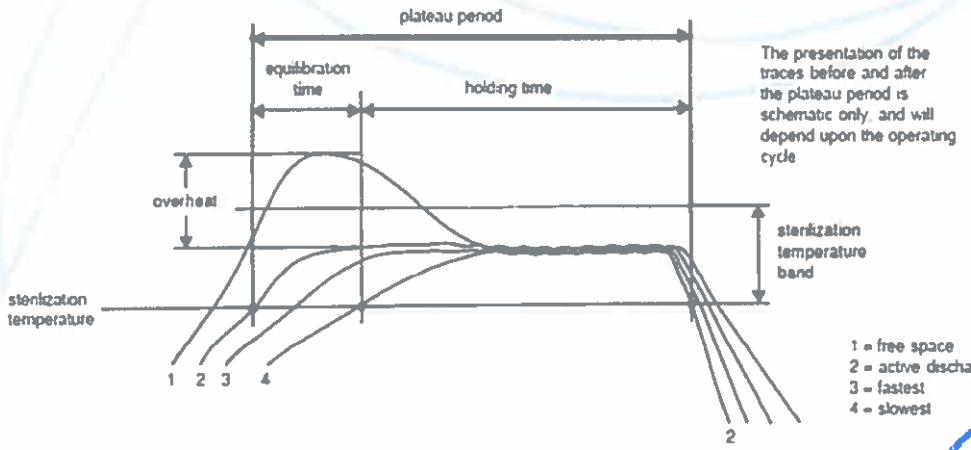
Note: Any amendment will be indicated with italic and bold font.

2. INTRODUCION

2.1. Glossary/Abbreviations

- **Performance Qualification (PQ):** is defined as the process of obtaining and documenting evidence that the equipment as commissioned will produce an acceptable product when operated according to process specification and will consistently perform in accordance with the approved process method and specifications. PQ is the final step of qualification which consists of tests designed to show that sterilization conditions are attained throughout a production load. In principle, a PQ test is required for each loading condition that the sterilizer is intended to process.
- **Moist Heat sterilization:** The saturated steam sterilization process and air overpressure sterilization process are the most frequently used sterilization methods. The saturated steam sterilization process is often used for loading porous/hard goods and liquid loads. Items sterilized by moist heat must withstand high temperature exposure, and maintain their functionalities, including microbial barrier function after undergoing changes in heat, and pressure (positive pressure and vacuum in some conditions). For moist heat sterilization, temperatures of approximately 115 °C up to 134 °C with pressure are used.
- **Bioburden:** The number/type of viable microorganism's contamination an item. (i.e. the total number of microorganisms associated with a specific item prior to sterilization).
- **SAL:** Sterility Assurance Level, the SAL of a sterilizing process is the degree of assurance with which the process in question renders a population of items sterile.
- **SAL of 10^{-6}:** the probability of a single viable microorganism being present is one in one million.
- **Log Reduction:** reduce the surviving microbial population by 1 log or decrease the surviving population by a factor of 10 (i.e. 12-log reduction is the log reduction required achieving over-kill and a SAL of 10^{-6}).
- **Overkill Approach:** objective is to provide sufficient heat to provide a minimum of 10^{-6} probability of microbial survival regradless of the number and heat resistance of the naturally occuring microorganisms and accomblished by designing a sterilizing process that results in a 12-log reduction of microorganisms having a D-value of 1 minute. This approch requires minimal information about the product bioburden and a worst case bioburden assumption is used to determine the delivered lethality needed to achieve a Probability of a Non-Sterile Unit (PNSU) of 10^{-6} on or in the items being sterilized.
- **Colony Forming Unit (CFU):** A microbiological term that describes the formation of a single macroscopic colony after the introduction of one or more microorganisms to microbiological growth media. One colony forming unit is expressed as 1 CFU.
- **Biological Indicators (BI):** a thermophilic spore-former with high resistance to dry heat. The spore challenge is placed on a substrate positioned within the load or on a load item. If spores are used as intended by the BI manufacturer, the population and resistance information provided by the vendor can be used. They are used to verify the efficacy of certain sterilization processes.
- **D-value:** The time in minutes, of exposure at a given temperature that causes a one log logarithmic reduction or 90% reduction in the population of a specific microorganism.
- **Z-value:** temperature change required resulting in a 1-log reduction in D-value.

- **F-value (Lethality Factor):** The number of minutes to kill a specified number of microorganisms with a specified Z-value at a specific temperatrue. Fref is the calculated equivalent lethality (using a specified z-value) for a sterilization process, in terms of minutes at a reference temperature (Tref), delivered by a sterilization process to an item.
- **Heat-up Phase:** The phase of a process that occurs prior to the exposure phase. Process parameters are developed for this phase in order to meet applicable user requirements for load conditioning.
- **Slowest Point:** the point that take longest time (lag time) to achieve sterilization temperature.
- **Lag time:** it is the time ensuring that the slowest point reached to the minimum sterilization temperature.
- **Equilibrium Time:** The period which elapses between the attainment of the sterilization temperature in the chamber and the attainment of the sterilization temperature in all parts of the load.
- **Holding time (A.K.A. Exposure time):** The period during which the temperature in all parts of the chamber and the load is held within the sterilization temperature band. It Follows immediately after the equilibration time.
- **Exposure Phase:** The phase of the process in which the appropriate parameters are maintained within defined ranges for the time (exposure time or dwell period) and temperature determined to be necessary to achieve the desired lethality.
  NOTE: The holding time / exposure time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.
- **Plateau period:** The equilibration time plus the holding time.



2.2. Rationale

- The Performance Qualification (PQ) process is crucial in establishing the suitability of the Autoclave (MI-193) located at JAMJOOM PHARMA for its intended use, which involves moist heat sterilization. The PQ should generate accurate data to provide assurance that the Autoclave consistently meets the required standards and specifications for each sterilization method. By conducting a thorough PQ, we aim to validate the performance of critical systems within the Autoclave and ensure the efficiency of its sterilization process. Through a well-executed PQ, we can confidently establish the Autoclave's capability to deliver safe and effective sterilization outcomes, contributing to the overall quality and reliability of other operations.
- This PQ Protocol will provide the methodology of the qualification study, a guideline for documentation of the study and intended to assure the sterilization of the used loads when the equipment is operated in accordance with standard operating procedure.

2.3. Protocol Purpose

- To evaluate the heat distribution profiles and trends throughout the Autoclave located at JAMJOOM PHARMA.
- To describe the followed procedure used to perform the performance qualification of the Autoclave (MI-193) located at JAMJOOM PHARMA and to ensure uniformity and compliance with regulatory standards.
- These procedures are to be performed after any major modification of the equipment or relocation, any change in cycle parameters (set parameters), and for revalidation during appropriate intervals.
- To ensure and establish the heat penetration and log reduction efficiency of the Autoclave.
- To ensure that heat is sufficiently penetrating into the inner most portion of the loads subjected for sterilization to achieve desired temperature during the sterilization cycle.
- To ensure that the Autoclave performs as per the pre-defined parameters, quality attributes and according to the design specifications and pre-determined specifications under normal conditions.
- Determine the program design needed to fully sterilizing each load requirements.
- To identify the scope of qualification required by JAMJOOM PHARMA.
- To determine the responsibilities of TAG and JAMJOOM PHARMA.
- To clarify the rationale of this work scope and to clarify the rationale behind the chosen study design and its methodology.
- To identify the personnel of charge that will perform and follow-up this scope.

2.4. Protocol Scope

The scope of this protocol covers the performance qualification of the of the Autoclave (MI-193) located at JAMJOOM PHARMA for the following programs:

Scope			
No.	Cycle Description	Setting	Acceptance Criteria
1.	Liquid Cycle	@ 122 °C, for 20 min	(121+3) °C, NLT 20 min

2.5. Documents Execution Instructions

Prior to the initiation of Performance Qualification testing activities, this document will be generated, reviewed and approved by the appropriate personnel.

The testing specified in this approved Protocol will be conducted in accordance with the instruction detailed in the test cases.

Additional documentation requirements for protocol and report are as follows:

- Each person recording or reviewing the information in this document must complete the Signature Log
- After completing entries in the test cases, the initials and date of the individual responsible for the entry must be entered in the appropriate column
- Any blank entry space or box must have a line drawn through it, initialed, and dated.
- Any correction entry must be marked with a unique line drawn through the data to be changed, initialed, and dated. After correction, wrong data must remain readable.
- General datasheets and/or supporting documentation must be inserted as near to the related test datasheet as possible and must include the following information:
  - Reference to supplemented datasheet.
  - A unique id number (i.e. number of the supplemented datasheet + [a], [b], ... [aa], [ab], etc.
  - Page number.
- Supporting documentation not related to a specific datasheet can be attached at the end of this document. Attachments list has to be used to assign a unique id number.
- Attachments are to be intended both as digital/magnetic and paper supported.
- When approved vendor documentation (Protocols) is available and approved by JAMJOOM PHARMA, it will be possible to use it for the execution of the Protocol tests at the condition that the documentation meets the minimal requirements listed above.

Any test exception and failure verified during the protocol execution shall be noted on the "Deviation Report" form (Data Sheet Number 01.01.02.01 in Annex 01.01 (PQ Results Data Sheets)). Every exception and its conclusion (intended as foreseen corrective action results) shall be documented inside the related qualification summary.

2.6. Responsibilities

For the submission/approval, execution of this protocol and its final report, the responsibility of all personnel involved with the verification and documentation process are as follows:

2.6.1. JAMJOOM PHARMA

- Provide the necessary information needed for the Performance Qualification Protocol issue.
- Review and approve the protocol for compliance before qualification execution and ensure that the protocol aligns with regulatory requirements and company policies.
- Responsible for the operational aspects of the equipment being qualified.
- Provides access to the equipment being qualified, coordinate and assist in addressing any equipment-related issues that may impact the qualification process.
- Develop the project timeline and oversee the entire performance qualification project, including planning, coordination, and execution.
- Provides any documents required in the performance qualification test such as layouts.
- Assign tasks to the responsible team members, ensure adherence to the approved protocol, and manage communication with stakeholders.
- Ensure that the performance qualification process meets regulatory requirements and quality standards.
- Verify that the Autoclave is safe before execution and verify that the critical components have been calibrated.
- Determine the programs that is to be validated and provide the loads with its quantities that will be used during the qualification.
- Provide the biological indicators that will be used as indicator during the qualification.
- Monitor the study procedures, verify accuracy of results, and assess compliance with guidelines.
- Review any deviation in the deviation form, determine the corrective actions, and evaluate results of corrective measures and approve them.
- Review and approve the report and test results for compliance after execution and ensure that the report aligns with regulatory requirements and company policies.

2.6.2. TAG

- Design and prepare the qualification protocol, including all the recommendations and corrections that are required by JAMJOOM PHARMA.
- Review and approve the protocol for compliance before qualification execution and ensure that the protocol aligns with regulatory requirements and company policies.
- Execute the qualification only after this protocol has been approved by JAMJOOM PHARMA.
- Develop the project timeline and oversee the entire performance qualification project, including planning, coordination, and execution.
- Assign tasks to the responsible qualified team members, ensure adherence to the approved protocol, and manages communication with stakeholders.
- Assure that each instrument used for qualification is calibrated before and after the use and meets the criteria of the guideline.
- Distribute the monitoring devices, ensure data collection at specified interval and troubleshoot any technical issues incident by TAG.
- Conduct and oversee the technical aspects of the performance qualification study.
- Process raw data, generate reports, and communicate findings and any deviations to JAMJOOM PHARMA for further action.
- Assure that data from tests, executed by TAG, are properly recorded in an acceptable format on work sheet and on the report.
- Perform data analysis and interpret results to ensure the accuracy and reliability of the study and compare test results with the acceptance criteria and determine if it conform or not conform.
- Ensure that all original data, final form and tables are signed and dated, that these documents are attached to final Report or that a note with their storing location is specified.
- Ensure that the description of the tool used for tests, its serial number and its ID number are Reported on data collection worksheets and/or forms.
- Prepare the Performance Qualification Report including all the advices and amendments carried out by JAMJOOM PHARMA and submit for it for review and approval by the concerned JAMJOOM PHARMA departments.
- Maintain records of protocol, data collection procedures, calibration certificates, and final reports and ensure that all documentation is accurate, organized, and accessible for future reference.

2.7. Signature Log

Each person records, review and approve the information in this document must complete the signature log.

2.8. System Brief Description

The scope of this protocol intends to cover the performance qualification procedure 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

3. PERFORMANCE QUALIFICATION METHODOLOGY

3.1 Pre-Requisties

- Performance Qualification activities will only start after this Protocol is approved by the Officials deputed by JAMJOOM PHARMA.
- After this approval, the signed original of the Report will be filed in a suitable archive dedicated to Performance qualification/validation documents while another copy will be made available for working purposes.
- This copy, in which data gathered and recorded during qualification, and to which documents (such as layout, printouts, etc.) are attached, becomes the Qualification Report for the examined system.
- Once Performance Qualification Protocol is completed, any changes shall have to be checked, planned, and approved by JAMJOOM PHARMA and mentioned in the change history table.
- Any non-conformities encountered and any other discrepancies from acceptability criteria of this Protocol shall be recorded in the "Deviation Report" form (Data Sheet Number 01.01.02.01 in Annex 01.01 (PQ Results Data Sheets)).

3.2 Key Concepts

3.2.1 Sterilization Process General Concepts

- **Overkill Approach:** is utilized to assure that the level of sterility assurance regardless of the number and heat resistance of the bio-burden organisms in the load. Its objective is to provide sufficient heat to provide a minimum of 10^{-6} probability of microbial survival regardless of the number and heat resistance of the naturally occurring microorganisms and accomplished by designing a sterilizing process that results in a 12-log reduction of microorganisms having a D-value of 1 minute.
- **Types of Sterilization:** Choosing the right method of sterilization depends on the material being sterilized and the purpose of sterilization, see the below table.
- **D-value:** The time in minutes, of exposure at a given temperature that causes a one-log logarithmic reduction or 90% reduction in the population of a specific microorganism.
- **Z-value:** temperature change required resulting in a 1-log reduction in D-value.
- **F-value (Lethality Factor):** The number of minutes to kill a specified number of microorganisms with a specified Z-value at a specific temperature. Fref is the calculated equivalent lethality (using a specified z-value) for a sterilization process, in terms of minutes at a reference temperature (Tref), delivered by a sterilization process to an item.

Types of Sterilization
Moist Heat (Steam) Sterilization (This is the type applied in this sterilizer)
It is done under high temperature and high pressure in moist conditions (Ex. Autoclaves).
Usually in the approximately 115 °C up to 134 °C temperature range with pressure.
It can be used for loading porous/hard goods and liquid loads.
Biological indicators are usually used to verify the efficacy of the sterilization processes and to validate the equipment performance.
F_o-value: evaluates the effectiveness of steam sterilization. Z-Value equals to of 10 °C at a temperature of 121.1 °C (when the exact microorganism was unknown).

$$F_o = \Delta t \sum (10^{(T - Ts)/Z})$$

Where:

Δt : Time interval between two next measurements of (T).

L : Lethal Rate = $10^{(T - 121.1)/Z}$.

Ts : 121.1 °C.

T : Temperature of the sterilized product at time (°C)

Z : Temperature coefficient, assumed to be equal to (10 °C).

3.3 Associated Material and Equipment Description

To ensure that the temperature distribution in the equipment to be validated is adequately characterized, we should use a sufficient number of monitoring sensors along with suitable computer equipment and software to store and analyze the data. The selected sensors will:

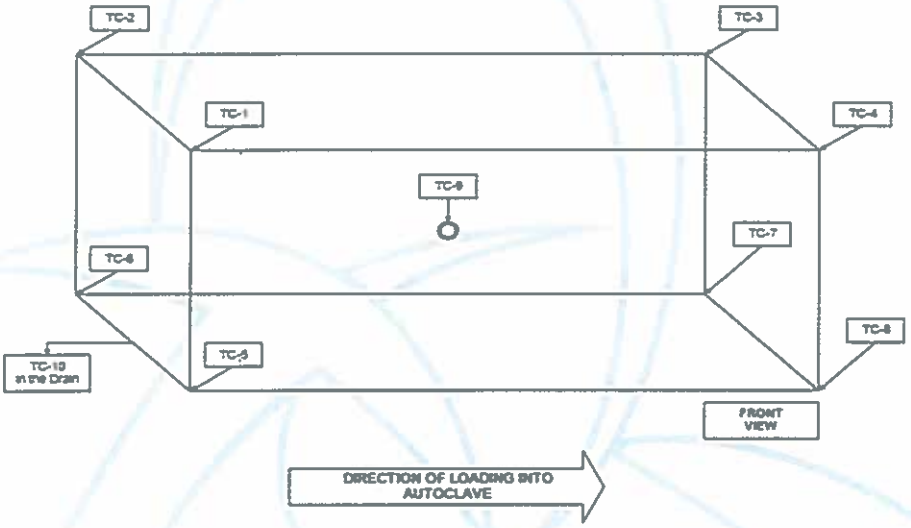
- be technically suitable for the specific validation task and for the intended operating environment.
- provide a reliable and continuous record of time-temperature data.
- have an appropriate temperature range so that all anticipated temperature extremes can be recorded.
- have a user-programmable data sampling period, allowing time intervals to be on 15 seconds (maximum).
- enable the recorded time-temperature data to be downloaded to a computer system for subsequent analysis.
- be verified before and after performing the validation using Pt-100 with digital indicator as a reference instrument. The verification should be at least at 3-points including the setting point and 1-point before and after the setting point with a guaranteed error of no more than ± 0.5 °C at each verification point. The verification results will be mentioned in the "Reference Equipment List and Calibration Verification" form (Data Sheet Number 01.01.03 in Annex 01.01 (PQ Results Data Sheets)).
- have a US National Institute of Standards and Technology (NIST)- traceable 3-point annual calibration certificate with a guaranteed error of no more than ± 0.5 °C at each calibration point.

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	Will be determined at the execution phase		
Data Loggers	01 sensors	(0) bar to (4) bar	± 5% of F.S	Will be determined at the execution phase		
For the detailed specification of the selected equipment, see point 2.3 in Annex 01.01 (PQ Results Data Sheets).						
The calibration certificates are attached in Annex-01.02 (Turn Over Package).						
The exact location of each sensor in Autoclave is specified in the layout, see point 3.7 in this protocol.						

3.4 Sensors Quantity and Distribution Locations Rationale

Calibrated sensors should be distributed evenly throughout the chamber interior in representative horizontal and vertical planes, including the center and all corners. One (1) sensor should be placed adjacent to the controlling probe (in drain) and at least one sensor should be placed next to the monitoring and control sensors. The homogeneity of the load and the loading pattern largely determine the number of temperature sensors needed. Using mixed loads could require an increase in the number of sensors being used. As per PDA Technical Report No. (1):

- A minimum of 10 sensors (preferred to be 12 sensors) or 5 sensors per 2.8 m^3 (100 ft^3) for large sterilizers are to be used for sterilizer validation but it has not given the volume of large autoclaves. A one pressure sensor must be there to validate the pressure in the case of autoclave validation.



3.5 Procedure Description

The following steps outline the methodology for conducting the performance qualification study for Autoclave:

Methodology	
Pre-requisite	Steps 1 to 6 must be completed before the mapping protocol can finally be approved.
Step (1)	**Designating the Techncial Team:** - See point "5. SIGNATURE LOG" including the list of the team members with their signatures/initials for traceability.
Step (2)	**Determining the system under qualification specifications:** - Document volume, drawings, and critical component locations to determine the number of sensors that will be required to perform the qualification.
Step (3)	**Defining Acceptance Criteria and Study Design:** - Base criteria and study design on product/equipment requirements and/or according to the customer requirement.
Step (4)	**Sensors Pre-Calibration Check:** - Sensors will be checked before tests execution at the setting point and at 1-point before and at 1-point after this setting point. For the pre-verification results, see (Data Sheet Number 01.01.03.02 in Annex 01.01 (PQ Results Data Sheets).
Step (5)	**Determination of Sensors Locations:** - As explained in point 3.4, we will need 12 sensors to perform accurate qualification for this Autoclave.
Step (6)	**Recording Sensors Locations:** - The exact location of each sensor in the Autoclave is specified in the layout, see point 3.7 in this protocol. - For the table of sensors locations and the controller set points, see data sheets no. (01.01.01) in Annex 01.01 (PQ Results Data Sheets).
Step (7)	**Labelling and Programming EDLMs:** - Assign unique IDs and record serial numbers of each sensor. - Program each sensor with the same sampling interval which will be 15 seconds. Set the same start time for all units. - For the exact study design, see point 2.4 in Annex 01.01 (PQ Results Data Sheets).
Step (8)	**Fixing Sensors in Position:** - Position the sensors in a proper way so that they cannot be damaged or displaced during the course of routine operations. - In case of penetration cycles, arrange the BIs beside each sensor.
Step (9)	**Performing Validation Exercise:** - For the exact study design including study period details, see point 2.4 in Annex 01.01 (PQ Results Data Sheets).

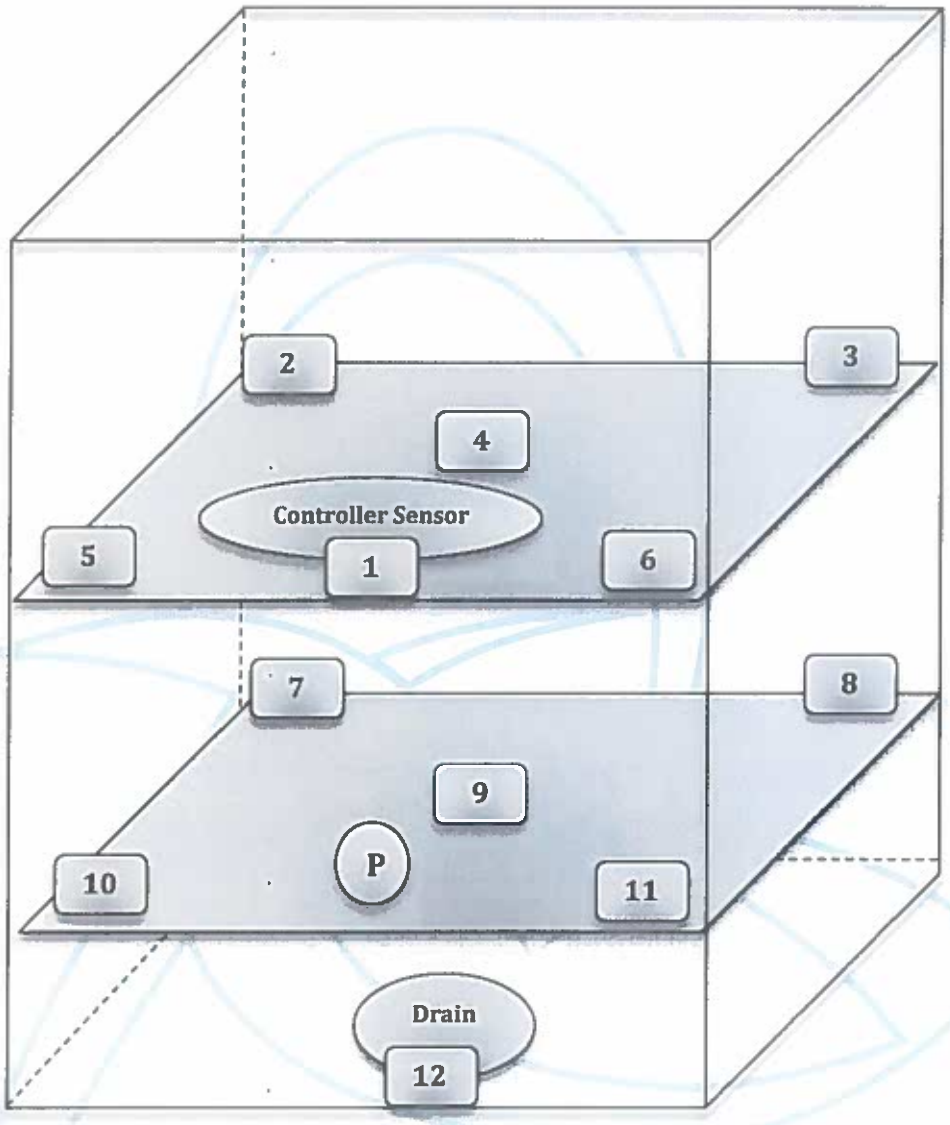
Step (10)	**Data Analysis:** - Download the sensors readings and consolidate the data for the study analysis. - For each validation cycle calculate the following parameters: Calculate the minimum F-value and its location. Determine minimum recorded sterilization temperature and its location. Determine maximum recorded sterilization temperature and its location. Determine the slowest heating point. Determine the coolest and hottest points. Determine the equilibration time. Determine plateau period. Determine holding time (exposure time).
Step (11)	**Sensors Post-Calibration Check:** - Sensors will be checked after tests execution at the setting point and at 1-point before and at 1-point after this setting point. For the post-verification results, see (Data Sheet Number 01.01.03.03 in Annex 01.01 (PQ Results Data Sheets).

3.6 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 F_o-value	≥ 20 (as per customer requirement)

Cycle No.	Cycle Description	Load Description	Sample Frequency
1.	Liquid	will be determined at the execution phase	15 seconds

3.7 Endorsed Layout and Sensors' Distribution



3.8 Acceptance Criteria

The general acceptance criteria for PQ stage specify that the results of all the locations envisaged in this Protocol, when correctly run and documented in the attached forms, confirm the expected result.

3.9 Results Evaluation

After conducting the heat distribution study, the results will be thoroughly evaluated to assess temperature distribution and uniformity within the Autoclave. Key aspects to consider in the final report after the evaluation include:

- Comparison of results against set criteria and industry standards.
- Identification of temperature variations, and hottest/coolest points.
- Full description for the loading pattern.
- Equilibrium time for each cycle.
- F-value for each monitoring location and determining the minimum F-value.

3.10 Deviation Report

Any observed deviations from acceptance criteria encountered while running the performance qualification shall be recorded in the specific form named "Deviation Report" enclosed in (Data Sheet Number 01.01.02.01 in Annex 01.01 (PQ Results Data Sheets)) to be reported to JAMJOOM PHARMA for taking and following up the corrective actions for those deviations.

3.11 Conclusion

- Based on the results of the performance qualification study, a conclusion will be drawn regarding the effectiveness of of the sterilization capaability of the sterilizer. The conclusion will summarize the key findings of the study and address whether the equipment meets the required specifications for intended use.

3.12 Final Performance Qualification Report

After all the studies envisaged in this Performance Qualification Protocol, a Final Performance Qualification Report shall be issued. This Report consists of multiple sections.

In the first section, the results of all the studies run during Performance Qualification stage shall be recorded in the proper table.

The next section provides a table where deviations encountered, if any, shall be recorded, also specifying its description and the deviation closing date.

The last section consists of one page and shall attest revision and approval of all results obtained by appointed Officials.

When all tests are performed and deviations are closed, the Report will be finally approved by the appointed Officials.

3.13 Re-Validation and Management of Changes/Modifications

- Any major changes/modifications made to the equipment after its qualification shall be recorded in "Change Control" procedure of JAMJOOM PHARMA.
- Each significant change or modification made to the system after this Protocol has been tested requires that the need to re-submit the equipment to another Re-Qualification procedure is evaluated. Reasons shall be given for not proceeding to a new Re-Qualification.

4. REFERENCES

(1) Health Technical Memorandum (HTM 01-01 C): Management and decontamination of surgical instruments (medical devices) used in acute care - Part B: Common elements, Jul., 2016.

(2) Health Technical Memorandum (HTM 01-01 C): Management and decontamination of surgical instruments (medical devices) used in acute care - Part C: steam sterilization, Jul., 2016.

(3) Parenteral Drug Association (PDA), Technical Report No. (1), (2007) – Validation of Moist Heat Sterilization Processes.

5. SIGNATURE LOG

Printed Name	Title	Company / Department	Initials	Signature
Shimaa Badr	Technical Office Engineer	TAG	S.B	Shaimaa
Mahmoud Makhlouf	Site Engineer	TAG	M.M	M. Makhlouf
Noha Essam	Technical Office Senior	TAG	N.E	Noha Essam
Ahmed Tarek	Technical Manager	TAG	A.T	