To verify that this document is original, please check this QR code

VOL-01

STEAM QUALITY TEST REPORT

FOR

SIP TANK

OF

JAMJOOM PHARMA

EL-OBOUR CITY

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

Package Content:

VOL-01 Steam Quality Test Report

Annex-01.01) Turn Over Package (Attachments)

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. REPORT REVIEW AND APPROVAL

The signatures below signify the approval of the format and content of the 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.T.L.	TAG	29/05/2025	

TAG Inspector(s)

Name	Title	Company	Date	Signature
Mahmoud Makhlouf	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	

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	29/05/2025

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

2. INTRODUCION

2.1. Glossary/Abbreviations

- **Steam Quality:** Refers to the condition or purity of steam, typically involving dryness fraction, non-condensable gases, and superheat content.
- **Dryness Fraction:** The proportion of steam that is dry (i.e., vapor) compared to the total mass. A dryness fraction of 0.95 means 95% dry steam and 5% water.
- **Non-Condensable Gases (NCGs):** Gases such as air, CO_2, or nitrogen that do not condense with steam and can affect heat transfer efficiency and sterilization.
- **Superheat:** The temperature of steam above its boiling point at a given pressure. Superheated steam is not desirable in sterilization.
- **Saturated Steam:** Steam that is in equilibrium with water at the same temperature and pressure – contains no superheat and is ideal for sterilization.

2.2. Test Rationale and Purpose

- The steam qualification process is crucial in establishing the effectiveness of the STEAM QUALITY FOR SIP TANK located at JAMJOOM PHARMA to produce pure steam. The qualification should generate accurate data to provide assurance that the STEAM QUALITY FOR SIP TANK consistently meets the required standards and specifications. By conducting a thorough steam qualification, we aim to ensure the efficiency of the steam to be used in the sterilization process. Through a well-executed steam qualification, we can confidently establish the STEAM QUALITY FOR SIP TANK's capability to produce effective pure steam, contributing to the overall quality and reliability of the sterilization operations.
- Steam quality testing is performed to verify that the steam supply assures product sterility. It is a requirement of manufacturers and processors of sterile product. Excess non-condensable gases trapped in the steam supply can have the same effect as inadequate air removal. Air is an excellent insulator and can inhibit the heating process. Air pockets can form in areas and prevent the steam from reaching all parts of the sterilizer load. Moisture is essential to the sterilization process as it facilitates the denaturing of proteins and coagulation of cell walls. Superheated steam will act as hot air until the temperature drops to its boiling point. Until this happens, the condensation required for sterilization will not be present. Superheated steam will require sustained high temperatures and longer hold times in order to assure sterilization. Excess moisture in the steam indicated by a lower Dryness value will reduce the energy present in the steam. This can also cause wet loads. The packaging for sterile products is designed to prevent reinfection when dry. However, these properties are diminished when wet.

2.3. Report Scope

The scope of this report covers the steam qualification of the STEAM QUALITY FOR SIP TANK located at JAMJOOM PHARMA.

2.4. Documents Execution Instructions

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

Additional documentation requirements for 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.
- Any test exception and failure verified during the execution shall be noted on the “Deviation Report”. Every exception and its conclusion (intended as foreseen corrective action results) shall be documented inside the related qualification summary.

2.5. Responsibilities

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

2.5.1. COPMANY_NAME

- Provide the necessary information needed for the report issue.
- Responsible for the operational aspects of the equipment being qualified.
- Provides access to the system being qualified, coordinate and assist in addressing any system-related issues that may impact the qualification process.
- Develop the project timeline and oversee the entire qualification project, including planning, coordination, and execution.
- Provides any documents required in the qualification test.
- Assign tasks to the responsible team members, and ensure that the qualification process meets regulatory requirements and quality standards.
- Verify that the STEAM QUALITY FOR SIP TANK is safe before execution.
- 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.

2.5.2. TAG

- Design and prepare the qualification report, including all the recommendations and corrections that are required by JAMJOOM PHARMA.
- Develop the project timeline and oversee the entire qualification project, including planning, coordination, and execution.
- Assign tasks to the responsible qualified team members, and ensure that the qualification process meets regulatory requirements and quality standards.
- Assure that each instrument used for qualification is calibrated and meets the criteria of the guideline.
- Conduct and oversee the technical aspects of the qualification study.
- Troubleshoot any technical issues incident by TAG.
- 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 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 report including all the advices and amendments pointed out by JAMJOOM PHARMA and submit for it for review and approval by the concerned JAMJOOM PHARMA departments.
- Maintain records of data collection procedures, calibration certificates, and final reports and ensure that all documentation is accurate, organized, and accessible for future reference.

2.6. Signature Log

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

2.7. System Brief Description

The scope of this report intends to cover the qualification procedure and results of STEAM QUALITY FOR SIP TANK located at JAMJOOM PHARMA with the following description:

System Brief Description	
Description	**SIP TANK**
Manufacturing	**NA**
Model/ S.N.	**NA**
Code	**--**
Location	**--**

3. METHODOLOGY

3.1 Test Objective

Generate documented evidence which provides the standard operation procedure steps that must be followed at using the apparatus to test the steam quality. measuring of non-condensable gases, dryness and superheat.

3.2 Test Procedures

3.2.1 Non-Condensable Test Performance:

3.2.1.1 Before starting the test ensure the cooling water valve is fully open and the steam valve is closed.

3.2.1.2 Turn on the water supply by supplying power to the pump. After ensuring that the cooling water is leaving the outlet pipe, the main steam valve may be slowly opened. Live steam and boiling water could discharge from the condensation collecting chamber if insufficient cooling water is available and present a hazard. In any event, precautions should be taken. Do not look into the collecting chamber and wear eye protection.

3.2.1.3 Slowly open the steam valve and by reducing or increasing the flow through the steam and water valves, obtain a flow of condenses that will give a temperature of between 70 C° and 90 C°, as indicated on the dial temperature gauge.

3.2.1.4 Fill the condensation collection chamber with water either by filling it with water from an external source or allowing condensation to accumulate.

3.2.1.5 Open the burette cock and draw up condense into the burette with the rubber bulb provided, to get a water level near the top. Remember to isolate the burette from the rubber bulb by shutting the burette cock before testing commences.

3.2.1.6 Fill the condensation collection chamber with more water, until it overflows.

3.2.1.7 Ensure that the sterilizer chamber is empty except the normal furniture etc. Select a porous load/equipment cycle and start a run.

3.2.1.8 When the steam supply to chamber first opens, ensure the measuring cylinder is empty, by emptying it.

3.2.1.9 Zero or make a note of the water level in the burette

3.2.1.10 Any non-condensable gases present in the steam being sampled will rise to the top of the burette. The overflow formed by the condensate and the water displaced by the gases, will collect in the measuring cylinder.

3.2.1.11 When at least 100 ml of condenses has been collected in the measuring cylinder note the volume of gas collected in the burette (VG) and the volume of water collected in the measuring cylinder (Vc).

3.2.1.12 Calculate the amount of non-condensable gases as follows in ml per 100ml of collected condensate using the following formula:

$$C_{NCG} = \frac{V_G}{V_C - V_G} \times 100$$

Where:

- VG: Volume of water displaced from the burette in (ml)
- VC: Volume of water collected in he graduated cylinder in (ml)
- CNCG: Content of non-condensable gases in (ml) per 100ml condensate from steam

3.2.2 Superheat Test Performance:

3.2.2.1 Ensure the sterilizer chamber is empty except for the usual chamber furniture. Select and start a porous load/equipment cycle.

3.2.2.2 From the measured temp., note the average temp. in the steam service pipe (for use in the dryness test) & in the expansion tube (Te) when the steam supply to the chamber first opens.

3.2.2.3 Calculate the superheat in C° from the following equation:

$$\text{Superheat} = Te - T0$$

Where:

- T0 is the boiling point of water at local atmospheric pressure.
- Te (Avg. temp. in the steam service pipe – Temp. in expansion tube).

3.2.3 Dryness Test Performance:

Before performing the test ensure the pitot hole is not restricted as this will lead to false results. This is best done prior to fitment for safety reasons. A long heat up time for the flask reaching ~80°C is not normal. It should take no more than 5 minutes.

3.2.3.1 Weigh the whole assembly including pipe and clips and note the weight (M1).

3.2.3.2 Remove the stopper and tube assembly and pour 650 +/- 50 ml of cold water (below 27C°) into the flask. Replace the stopper and tube assembly, weigh the flask and record the mass (M2).

3.2.3.3 Support the flask close to the Pitot tube taking care to avoid the issuing steam. Ensure that the rubber tube and flask are protected from excess heat and draughts. Do not connect it to the Pitot tube yet.

3.2.3.4 Introduce the second temperature sensor through the shorter of the two pipes into the water in the flask. Agitate the flask and note the temperature of the water in the flask (T0).

3.2.3.5 Ensure the sterilizer is empty except for the usual chamber furniture. Select and start a porous load/equipment cycle.

3.2.3.6 When the steam supply valve to the chamber first opens, connect the rubber tube to the Pitot tube. This will require the tester to be in close proximity to the steam issuing from the Pitot tube and extreme care is required to avoid scalding and/or burning. Gloves, overalls and eye protection must be worn.

3.2.3.7 Observe/record the steam temperature for the duration of the test and on completion of the test calculate the average temperature (TS).

3.2.3.8 When the temperature in the flask is approximately 80 C°, disconnect the rubber tube from the stainless-steel tube taking the same precautions as when fitting. Agitate the water in the flask to make sure it is thoroughly mixed. Note the temperature of the water (T1).

3.2.3.9 Remove temp. probe & weigh the flask & stopper assembly including pipe & clips & note the mass in Kg (Mf).

3.2.3.10 Calculate the dryness value by using the following formula:

$$D = \frac{(T_2 - T_1)\left[C_{pw}(m_s - m_e) + A\right]}{L(m_f - m_s)} - \frac{(T_3 - T_2)\,C_{pw}}{L}$$

Where:

- L: Latent heat of dry saturated steam at T3 (KJ/Kg)
- me: Mass of vacuum flask & Rubber stopper, pipes & Tubes in (Kg)
- ms: Mass of vacuum flask, Water Change, Rubber stopper, pipes & Tubes in (Kg)
- mf: Mass of vacuum flask, Water Change, Condensate Rubber stopper, pipes & Tubes in (Kg)
- T1: Initial Temp. of water in the vacuum flask (°C)
- T2: Final Temp. of water in the vacuum flask (°C)
- T3: Temp. of saturated steam delivered to the sterilizer in (°C)
- Cpw: Specific heat capacity of water (4.18 KJ/Kg K)
- A: Effective heat capacity of the apparatus (0.23 Kg/K)

3.3 Acceptance Criteria

3.3.1 Non-Condensable Test:

- The test should be considered satisfactory if the level of non-condensable gases does not exceed 3.5%.
- The test should be done three times in total to check consistency. If the results of the tests differ significantly, then the cause should be investigated before proceeding further.

3.3.2 Superheat Test:

- The test should be considered satisfactory if the superheat measured in the expansion tube does not exceed 25 °C.

3.3.3 Dryness Test:

- The test should be considered satisfactory if the following requirements are met:

a. The dryness value is not less than 0.90 (if metal loads are processed, the dryness value should not be below 0.95).

b. Throughout the operating cycle, the temperature measured in the steam service pipe is within 3 °C of that measured during the superheat test.

3.4 Results Evaluation and Conclusion

After conducting the study, the results will be thoroughly evaluated to confidently establish the STEAM QUALITY FOR SIP TANK's capability to produce effective pure steam, contributing to the overall quality and reliability of the sterilization operations.

3.5 Deviation Report

Any observed deviations from acceptance criteria encountered while running the performance qualification shall be recorded in the specific form named “Deviation Report” to be reported to JAMJOOM PHARMA for taking and following up the corrective actions for those deviations.

3.6 Re-Validation and Management of Changes/Modifications

- Any major changes/modifications made to the system after its qualification shall be recorded in “Change Control” procedure of JAMJOOM PHARMA.
- Each significant change or modification made to the system after the system has been tested requires that the need to re-submit the system to another Re-Qualification. 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 C: steam sterilization, Jul., 2016.

5. TEST REULSTS

5.1. Superheat Test Data Sheet

Superheat Test		
Superheat Temperature Value (°C)		
Cycle 1	Cycle 2	Cycle 3
0.7 °C	0.4 °C	0.6 °C
Acceptance Criteria	≤ 25°C	
Test Result (Pass or Fail)	Pass	

5.2. Non-Condensable Gases Test Data Sheet

Non-Condensable Gases Test		
Non-condensable Gas Level (%)		
Cycle 1	Cycle 2	Cycle 3
1.3 %	1.7 %	1.1 %
Acceptance Criteria	NMT 3.5%	
Test Result (Pass or Fail)	Pass	

5.3. Dryness Test Data Sheet

Dryness Test		
D-Value		
Cycle 1	Cycle 2	Cycle 3
0.98	0.96	0.95
Acceptance Criteria	≥ 0.95	
Test Result (Pass or Fail)	Pass	

NOTES:

	Reviewed By (TAG)	Reviewed By (JAMJOOM PHARMA)
Name	Ahmed Tarek	
Signature		
Date	29/05/2025	

6. REFERENCE INSTRUMENTS CALIBRATION VERIFICATION

Reference Instruments List				
Instrument Description			CALIBRATION	
No. Instrument Description	Manufacturer/ Model	Code/S.N.	Most recent calibration date	Calibration Due Date
Pt-100 with digital indicator	GMH/3710	N.Pt100/117	Jun., 2024	Jun., 2025
Thermocouple type K with digital indicator	Testo/175 T3	N.TC-31/1	Dec., 2024	Dec., 2025

	Reviewed By (TAG)	Reviewed By (JAMJOOM PHARMA)
Name	Ahmed Tarek	
Signature		
Date	29/05/2025	

7. 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:

8. LIST of ATTACHMENTS

List of Attachments		
Attachment No.	**Description**	**Location**
01.01.01.01	Site Sheet Reports	Annex-01.01 (Turn Over Package)
01.01.01.02	Devices References	Annex-01.01 (Turn Over Package)
01.01.01.03	Inspection Certificate	Annex-01.01 (Turn Over Package)

9. SIGNATURE LOG

Printed Name	Title	Company / Department	Initials	Signature
Shimaa Badr	Technical Office Team Leader	TAG		
Mahmoud Makhlouf	Site Engineer	TAG		
Noha Essam	Technical Office Senior	TAG		
Ahmed Tarek	Technical Manager	TAG		

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:

	Name	Signature	Title	Company	Date
Approved by	Shimaa Badr		T.O.E	TAG	
Approved by	Mahmoud Makhlouf		P.E.	TAG	
Approved by	Noha Essam		SR. T.O.E	TAG	
Approved by	Ahmed Tarek		T.M.	TAG	
Approved by			T.M.	TAG	
Approved by					
Approved by					