



Pharmaceutical Container Closure Integrity Testing Checklist

Test Planning & Preparation

Ensuring proper test scope, methodology selection, and equipment readiness.

Test Objective(s)

Write something...

Test Methodology

- ☐ Vacuum Decay
- ☐ Pressure Decay
- ☐ Helium Leak Testing
- ☐ Direct Leak Testing

Sample Size (Units)

Enter a number...

Planned Test Start Date

Enter date...

Planned Test End Date

Enter date...

Acceptance Criteria Source

- ☐ Company Standard
- ☐ Regulatory Guidance
- ☐ Client Requirement

Equipment Calibration & Verification

Confirming accuracy and reliability of testing equipment.

Last Calibration Date

Enter date...

Calibration Frequency (in months)

Enter a number...

Temperature Reading During Calibration (°C)

Enter a number...

Pressure Reading During Calibration (PSI)

Enter a number...

Calibration Standard Used

- ☐ NIST traceable standard
- ☐ In-house standard
- ☐ Other - Specify in Long Text

Calibration Details/Comments (if 'Other' selected above)

Write something...

Calibration Certificate (PDF)

 Upload File

Technician Signature

Sample Selection & Handling

Ensuring representative samples are selected and handled appropriately.

Number of Samples Selected

Enter a number...

Sampling Method

- ☐ Random Sampling
- ☐ Stratified Sampling
- ☐ Judgmental Sampling

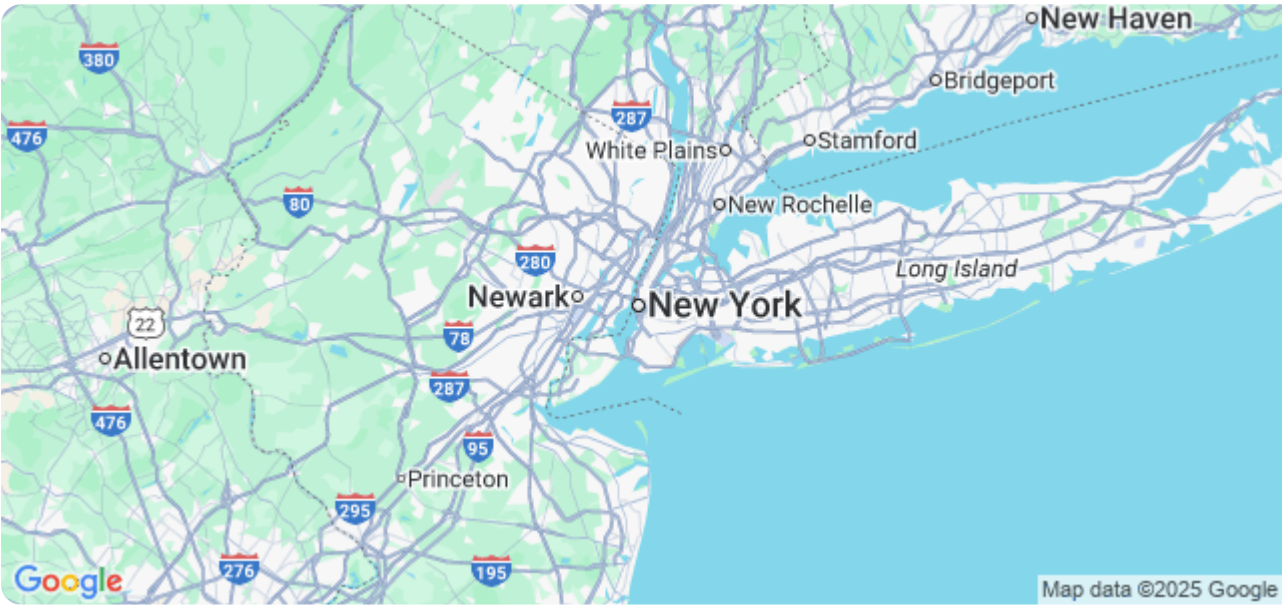
Sample Collection Date

Enter date...

Sample Collection Time

Sample Collection Location

 Set My Current Location



Sample Description (Appearance, Condition)

Write something...

Container Type

- ☐ Glass
- ☐ Plastic
- ☐ Metal

Sample Collector Signature

Leak Testing Procedure Adherence

Verifying adherence to established leak testing protocols (e.g., vacuum decay, pressure decay, helium leak testing).

Leak Testing Method

- ☐ Vacuum Decay
- ☐ Pressure Decay
- ☐ Helium Leak Testing
- ☐ Other (Specify)

Vacuum Level (mmHg)

Enter a number...

Pressure (psi)

Enter a number...

Leak Rate Limit (cc/min)

Enter a number...

Test Duration (minutes)

Specific Procedure Steps Followed (Detailed)

Write something...

Procedure Version Used

- ☐ Version 1.0
- ☐ Version 1.1
- ☐ Version 1.2
- ☐ Other (Specify)

Operator Signature

Data Acquisition & Recording

Accurate and complete recording of test data and observations.

Vacuum Decay Test Pressure (mmHg)

Enter a number...

Vacuum Decay Test Duration (seconds)

Enter a number...

Leak Rate (cc/second)

Enter a number...

Date of Test

Enter date...

Time of Test Start

Observations During Testing

Write something...

Test Result (Pass/Fail)

☐ Pass

☐ Fail

Operator Signature

Results Evaluation & Acceptance Criteria

Comparison of results against predetermined acceptance criteria and assessment of container closure integrity.

Leak Rate (ml/min)

Enter a number...

Vacuum Decay Constant (k-value)

Enter a number...

Method Used (e.g., Vacuum Decay, Pressure Decay, Helium)

- ☐ Vacuum Decay
- ☐ Pressure Decay
- ☐ Helium Leak Testing
- ☐ Other - Specify in Long Text

Detailed Result Commentary

Write something...

Pass/Fail Determination

- ☐ Pass
- ☐ Fail
- ☐ Conditional - Requires Further Investigation

Justification for Pass/Fail Determination

Write something...

Date of Result Evaluation

Enter date...

Evaluator Signature

Deviation Management & Investigation

Documentation and investigation of any deviations from expected results or acceptance criteria.

Detailed Description of Deviation

Write something...

Date of Deviation Occurrence

Enter date...

Time of Deviation Occurrence

Severity Level (e.g., Minor, Moderate, Major)

- ☐ Minor
- ☐ Moderate
- ☐ Major

Quantity Affected (if applicable)

Enter a number...

Root Cause Analysis

Write something...

Corrective Action Plan

Write something...

Corrective Action Completion Date

Enter date...

Investigator Signature

Report Generation & Review

Compilation of test results and conclusions into a comprehensive report for review and approval.

Executive Summary of Findings

Write something...

Number of Containers Tested

Enter a number...

Number of Failed Containers

Enter a number...

Overall Conclusion (Pass/Fail/Conditional)

- ☐ Pass
- ☐ Fail
- ☐ Conditional

Detailed Description of Anomalies (if any)


Write something...

Report Issue Date

Enter date...

Reviewer Signature

Supporting Data/Graphs (optional)

 Upload File

Maintenance and Cleaning of Equipment

Ensuring equipment is properly maintained and cleaned after testing.

Last Cleaning Date

Enter date...

Cleaning Procedure Followed (Detailed Description)

Write something...

Cleaning Solution Concentration (%)

Enter a number...

Areas Cleaned (Check all that apply)

- ☐ Exterior Surfaces
- ☐ Sensor Ports
- ☐ Internal Components
- ☐ Fluid Pathways
- ☐ Power Supply

Cleaning Verification Photos (Optional)

 Upload File

Cleaning Effectiveness Verification Method

- ☐ Visual Inspection
- ☐ Residue Testing
- ☐ Other (Specify)

Other Method Description (if selected)

Write something...

Documentation Review and Traceability

Review of all associated documentation for completeness and traceability.

Document Review Date

Enter date...

Summary of Document Review Findings

Write something...


Document Status

- ☐ Approved
- ☐ Rejected
- ☐ Revised

Document Revision Number

Enter a number...

Upload Reviewed Document (if revised)

 Upload File

Reviewer Signature

Associated Batch/Lot Number

Write something...