



Pharmaceutical Packaging Integrity Checklist

Primary Packaging Material Assessment

Evaluation of the container closure system's material properties and suitability for drug compatibility.

Material Specification Review Summary

Write something...

Material Lot Status

- ☐ Approved
- ☐ Pending Approval
- ☐ Rejected


Material Thickness (mm)

Enter a number...

Density (g/cm³)

Enter a number...

Material Certificate of Analysis (CoA)

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Drug Compatibility Assessment Status

- ☐ Complete
- ☐ In Progress
- ☐ Not Required

Observed Material Characteristics

Write something...

Container Closure Sealing Integrity

Assessment of seal integrity, including visual inspection, leak testing (vacuum, pressure, dye penetration), and seal strength testing.

Vacuum Leak Test Pressure (inches of water)

Enter a number...

Vacuum Leak Test Duration (seconds)

Enter a number...

Leak Test Result

- ☐ Pass
- ☐ Fail
- ☐ NA

Leak Test Failure Description (if applicable)

Write something...

Dye Penetration Test Performed?

- ☐ Yes
- ☐ No

Seal Image (if applicable)

 Upload File

Seal Strength (N)

Enter a number...

Leak test performed date

Enter date...

Dimensional Accuracy & Tolerances

Verification that container dimensions and tolerances meet specifications to ensure proper dosing and functionality.

Container Height (mm)

Enter a number...

Container Diameter/Width (mm)

Enter a number...

Label Height (mm)

Enter a number...

Label Width (mm)

Enter a number...

Closure Height (mm)

Enter a number...

Closure Diameter (mm)

Enter a number...

Measurement Unit

☐ mm

☐ cm

☐ inches

Labeling & Identification

Confirmation that labeling is accurate, legible, and securely affixed, including lot numbers, expiry dates, and warnings.

Product Name

Batch Number

Manufacturing Date

Expiry Date


Label Orientation

- ☐ Vertical
- ☐ Horizontal

Label Material

- ☐ Paper
- ☐ Polypropylene
- ☐ Other

Label Image (for Reference)

 Upload File

Packaging Performance Testing

Evaluation of the packaged product's resistance to various stresses (e.g., vibration, compression, temperature) mimicking distribution conditions.

Drop Height (cm)

Enter a number...

Vibration Frequency (Hz)

Enter a number...

Temperature (Celsius)

Enter a number...

Humidity (%)

Enter a number...

Observed Damage (if any)

Write something...

Pass/Fail Result

☐ Pass

☐ Fail

Test Date

Enter date...

Test Data/Images

 Upload File

Tamper Evidence Evaluation

Assessment of tamper-evident features and their effectiveness in detecting unauthorized access.

Tamper-Evident Feature Type

☐ Child-Resistant Closure

☐ Sealed Unit Dose

☐ Blister Pack

☐ Shrink Wrap

☐ Tamper-Evident Tape

Number of Tamper Indications Present

Enter a number...


Indicator Integrity Status

- ☐ Intact
- ☐ Compromised
- ☐ Missing

Detailed Observation of Tamper Evidence

Write something...

Supporting Photographs

 Upload File

Compliance with Specifications

- ☐ Compliant
- ☐ Non-Compliant
- ☐ Not Applicable

Statistical Sampling Plan Verification

Confirmation that the sampling plan adheres to established statistical guidelines for accurate representation of the batch.

Sample Size (n)

Enter a number...

Acceptance Quality Limit (AQL)

Enter a number...

Sampling Method

- ☐ Random Sampling
- ☐ Systematic Sampling
- ☐ Stratified Sampling

Lot Size

Enter a number...

Justification for Sampling Plan Selection

Write something...

Criticality of Defect

- ☐ Critical
- ☐ Major
- ☐ Minor

Sampling Plan Review Date

Enter date...

Documentation Review

Verification of complete and accurate records related to packaging integrity assessments.

Document Review Date

Enter date...

Document Status (Reviewed/Approved/Rejected)

- ☐ Reviewed
- ☐ Approved
- ☐ Rejected

Review Comments/Observations

Write something...

Supporting Documentation (e.g., Test Reports)

 Upload File

Reviewer Signature

Document Revision Number

Enter a number...