ChecklistGuro

Pharmaceutical Stability Testing Checklist

Protocol Review & Preparation

Ensuring the stability testing protocol is complete, accurate, and compliant with relevant regulations.

Protocol Issue Date

Enter date...

Protocol Objective and Scope

Write something...

Batch Number(s) Included

Enter a number...

Stability Indicating Method Validation Status

- [ ] Validated
- [ ] Not Validated
- [ ] Validation in Progress

First Testing Date

Enter date...

Storage Conditions

- [ ] 25°C / 60% RH
- [ ] 30°C / 65% RH
- [ ] Other (Specify)

Sample Preparation & Labeling

Preparing and labeling samples according to the protocol, maintaining traceability and accuracy.

Batch Number

Enter a number...

Sample ID

Enter a number...

Sample Preparation Date

Enter date...

Sample Preparation Time

Packaging Configuration

- [ ] Primary Container
- [ ] Secondary Container
- [ ] Tertiary Container

Packaging Details (Size, Material)

Write something...

Sample Label Image (if applicable)

Upload File

Sample Status

- [ ] Approved
- [ ] Rejected

Preparer Signature

Storage Condition Monitoring

Verifying and documenting storage conditions (temperature, humidity, light) throughout the testing period.

Temperature (Celsius)

Enter a number...

Temperature (Fahrenheit)

Enter a number...

Relative Humidity (%)

Enter a number...

Start Date/Time

Enter date...

Time of Reading

Calibration Status

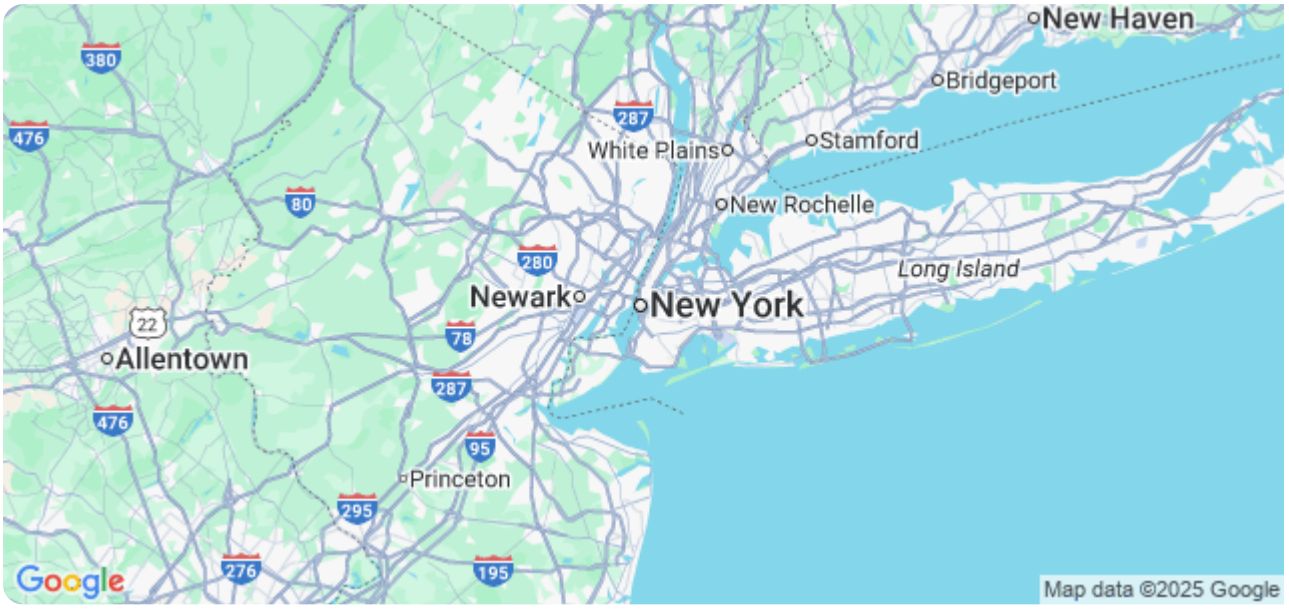
- [ ] Calibrated
- [ ] Needs Calibration

Comments/Observations

Write something...

Storage Location Identifier

Set My Current Location



Testing & Data Acquisition

Performing the specified tests, acquiring data, and ensuring data integrity.

Batch Number

Enter a number...

Testing Start Date

Enter date...

Testing Start Time

Temperature (°C)

Enter a number...

Humidity (%)

Enter a number...

Appearance

- [ ] Conforms
- [ ] Does Not Conform
- [ ] Unspecified

pH Value

Enter a number...

HPLC Chromatogram (if applicable)

Upload File

Data Analysis & Reporting

Analyzing stability data, generating reports, and documenting observations.

Batch Number

Enter a number...

Time Point (Days/Months)

Enter a number...

Assay Result (%)

Enter a number...

Impurity Level (ppm)

Enter a number...

Pass/Fail Status

- [ ] Pass
- [ ] Fail

Observations/Comments

Write something...

Date of Analysis

Enter date...

Analyst Signature

Deviation Handling & Investigation

Documenting and investigating any deviations from the protocol or unexpected results.

Description of Deviation

Write something...

Date of Deviation Occurrence

Enter date...

Time of Deviation Occurrence

Batch/Lot Number Affected

Enter a number...

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

- [ ] Minor
- [ ] Major
- [ ] Critical

Root Cause Analysis

Write something...

Corrective Actions Proposed

Write something...

Investigator Signature

Final Report Review & Approval

Reviewing the final report for accuracy, completeness, and adherence to regulatory requirements; obtaining necessary approvals.

Summary of Stability Data

Write something...

Report Version Number

Enter a number...

Report Classification (e.g., Confidential, Restricted)

- [ ] Confidential
- [ ] Restricted
- [ ] Public

Report Submission Date

Enter date...

Reviewer Signature

Reviewer Name

Write something...

Approver Signature

Approver Name

Write something...

Archiving & Documentation

Properly archiving all data, reports, and documentation related to the stability testing.

Date of Archiving

Enter date...

Summary of Archiving Process

Write something...

Scanned Archiving Log

Upload File

Archiving Location

- [ ] Physical Archive - Site A
- [ ] Physical Archive - Site B
- [ ] Electronic Archive - System X

Archive File Identifier/Reference Number

Enter a number...

Archivist Signature