



Pharmaceutical Stability Program Checklist


Program Setup & Documentation

Covers initial program design, SOPs, and documentation control.

Program Scope and Objectives

Write something...

Program SOP (Standard Operating Procedure)

 Upload File

Regulatory Framework Compliance (e.g., ICH, FDA)

- ☐ ICH Guidelines
- ☐ FDA Regulations
- ☐ Other (Specify)

Program Implementation Date

Enter date...

Document Control Number

Enter a number...

Responsibilities and Roles Defined

Write something...

Program Owner Approval

Protocol Development

Focuses on establishing stability testing protocols, including test conditions, acceptance criteria, and timeline.

Rationale for Selected Storage Conditions

Write something...

Container Closure System

- ☐ Primary Packaging
- ☐ Secondary Packaging
- ☐ Both

Number of Replicates per Batch

Enter a number...

Start Date of Stability Study

Enter date...

Time Points for Testing (Months)

Enter a number...

Parameters to be Tested

- ☐ Appearance
- ☐ Assay
- ☐ Impurities
- ☐ Moisture Content
- ☐ pH

Acceptance Criteria for Assay

Write something...

Sample Selection & Handling

Ensures appropriate sample selection, storage, and preparation for stability studies.

Batch Number

Enter a number...

Number of Samples Selected

Enter a number...

Packaging Configuration

- ☐ Primary Packaging Only
- ☐ Primary & Secondary Packaging
- ☐ Bulk Material

Sample Collection Date

Enter date...

Storage Condition Assignment

- ☐ 25°C/60%RH
- ☐ 30°C/65%RH
- ☐ Cool (2-8°C)
- ☐ Freezer (-20°C)

Sample Labeling Details

Write something...

Sample Storage Location

 Set My Current Location



Testing & Data Analysis

Covers analytical testing procedures, data analysis methods, and statistical evaluation.

Batch Number

Enter a number...

Testing Start Date

Enter date...

Testing Start Time

Temperature (°C)

Enter a number...

Humidity (%)

Enter a number...

pH Value

Enter a number...

Assay Result (%)

Enter a number...

Impurity A (ppm)

Enter a number...

Analytical Method

- ☐ HPLC
- ☐ GC
- ☐ UV-Vis

Trending & Reporting

Focuses on trend analysis, report generation, and data interpretation for stability assessment.

Batch Size Analyzed

Enter a number...

Report Generation Date

Enter date...

Summary of Trending Observations

Write something...

Overall Stability Status (Based on Trending)

- ☐ Acceptable
- ☐ Questionable
- ☐ Unacceptable

Number of Batches Included in Trend Analysis

Enter a number...

Justification for Stability Status

Write something...

Next Review Date of Trending Data

Enter date...

Deviation Management & CAPA

Addresses deviations from stability protocols and implementation of corrective and preventative actions.

Deviation Number

Enter a number...

Deviation Date

Enter date...

Description of Deviation

Write something...

Deviation Severity

- ☐ Minor
- ☐ Moderate
- ☐ Major

Root Cause Analysis

Write something...

Corrective Action Plan

Write something...

Corrective Action Completion Date

Enter date...

CAPA Approval Signature

Related Documents/Records

- ☐ Batch Record
- ☐ SOP
- ☐ Analytical Report
- ☐ Investigation Report

Periodic Review & Updates

Covers regular program reviews and updates to ensure ongoing effectiveness and compliance.

Last Review Date

Enter date...

Summary of Review Findings

Write something...

Areas Requiring Updates?

- ☐ Protocols
- ☐ Acceptance Criteria
- ☐ Testing Methods
- ☐ Archiving Procedures
- ☐ Regulatory Requirements

Rationale for Changes

Write something...

Next Review Cycle Length (Months)

Enter a number...

Impact Assessment?

- ☐ Minor
- ☐ Moderate
- ☐ Major

Reviewer Signature

Archiving & Data Retention

Focuses on secure archiving of stability data and adherence to retention time requirements.

Date of Data Archiving

Summary of Archiving Process

Number of Files Archived

Archiving Confirmation Document

 Upload File

Archiving Location

☐ Electronic Archive

☐ Physical Archive

Retention Period (Years)

Enter a number...

Description of Security Measures for Archive

Write something...