

### 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)  ① Upload File	
Regulatory Framework Compliance (e.g., ICH, FDA)    ICH Guidelines   FDA Regulations   Other (Specify)	
Program Implementation Date  Enter date	

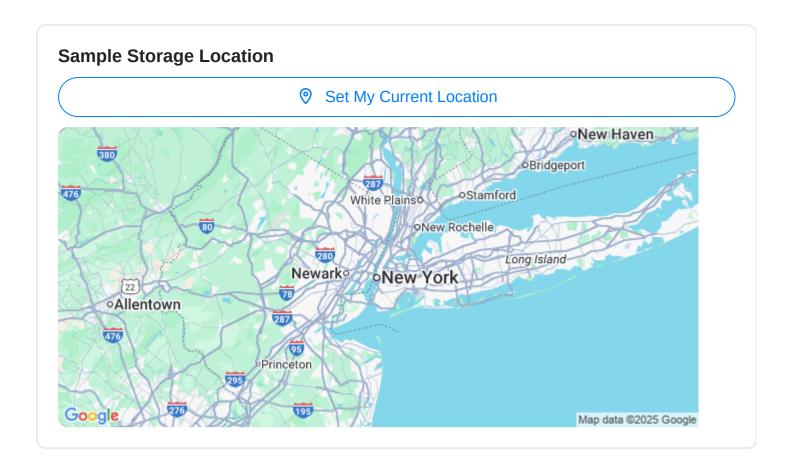
Document Control Number
Enter a number
Responsibilities and Roles Defined
Write something
Program Owner Approval
rotocol Development cuses on establishing stability testing protocols, including test conditions, acceptance eria, and timeline.
Rationale for Selected Storage Conditions
Write something

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	

### **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	



### **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 Mothod	
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	
Попассернале	
Number of Batches Included in Trend Analysis	
Enter a number	)
Justification for Stability Status	
Write something	

Enter date	
eviation Manageme	ent & CAPA
dresses deviations from stability p ventative actions.	protocols and implementation of corrective and
Deviation Number	
Enter a number	
Deviation Date	
Enter date	
Description of Deviation	
Write something	
Deviation Severity	
Minor	
<ul><li></li></ul>	

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.

Enter date	
Liner 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		
	$\supset$	
Archiving & Data Retention		
ocuses on secure archiving of stability data and adherence to retention time equirements.		
Date of Data Archiving		
Enter date		
Summary of Archiving Process		
Write something		
Number of Files Archived		
Enter a number		
Archiving Confirmation Document		
♣ Upload File		
Archiving Location		
☐ Electronic Archive ☐ Physical Archive		

escription of occu	rity Measures fo	AICHIVE	
Write something			`

**Retention Period (Years)** 

Enter a number...