

# SOP Template: Procedure for Sampling and Quality Testing of Materials

This SOP details the **procedure for sampling and quality testing of materials**, encompassing the selection of appropriate sampling methods, sample collection techniques, sample preservation and labeling, quality testing protocols, data recording and analysis, and reporting of results. The objective is to ensure that materials meet specified quality standards through systematic sampling and accurate testing, thereby maintaining product integrity and compliance with regulatory requirements.

## 1. Purpose

To outline a standardized procedure for sampling and quality testing of materials to ensure compliance with defined quality criteria and regulatory standards.

## 2. Scope

This SOP applies to all personnel involved in the sampling and quality testing of raw materials, intermediates, and finished products.

## 3. Responsibilities

- **Quality Assurance (QA):** Oversight, approval, and review of sampling and testing procedures.
- **Quality Control (QC):** Execution of sampling, performing tests, data analysis, and reporting.
- **Production/Receiving:** Coordination during material receipt and sampling activities.

## 4. Procedure

1. **Sampling Plan Development:**
  - Determine sampling method (random, stratified, systematic) based on material type and regulatory guidance.
  - Define sample size and number of samples per batch or lot.
2. **Preparation for Sampling:**
  - Clean and calibrate sampling tools and containers as per SOP.
  - Review safety data sheets (SDS) and wear appropriate PPE.
3. **Sample Collection:**
  - Collect samples aseptically using approved techniques.
  - Avoid contamination and cross-contamination.
  - Document sample source, time, date, and sampler's initials on the Sample Collection Form.
4. **Sample Preservation and Labeling:**
  - Label all containers with unique identifiers, description, collection date/time, and sampler's name.
  - Store samples under required conditions (e.g., temperature, protection from light) to prevent deterioration.
5. **Quality Testing Protocols:**
  - Perform testing in accordance with defined analytical methods and specifications.
  - Record test results promptly and accurately in designated logs or software.
6. **Data Recording and Analysis:**
  - Document all findings, calculations, and observations.
  - Analyze results for compliance with acceptance criteria.
7. **Reporting of Results:**
  - Prepare and review the Quality Test Report.
  - Notify relevant stakeholders of any out-of-specification (OOS) results for further action.

## 5. Documentation

- Sample Collection Form
- Test Data Sheets/Logs
- Quality Test Report

## 6. References

- Company Quality Manual
- Relevant regulatory guidelines (e.g., USP, ISO, GMP)

- Material-specific procedures and standards

## 7. Revision History

Version	Date	Description	Approved By
1.0	2024-06-20	Initial creation	QA Manager