

SOP: Sample Retention and Disposal Procedures

This SOP details the **sample retention and disposal procedures**, covering the proper handling, storage, documentation, and disposal of samples to ensure compliance with regulatory requirements and maintain data integrity. It includes guidelines for sample labeling, retention periods, storage conditions, chain of custody, criteria for sample disposal, and environmentally responsible disposal methods. The purpose is to safeguard sample quality, prevent contamination, and ensure timely and secure disposal of obsolete or expired samples.

1. Scope

This procedure applies to all personnel involved in the handling, retention, and disposal of samples within [Department/Facility Name].

2. Responsibilities

- **Sample Custodian:** Ensures compliance with this SOP. Maintains records and oversees retention and disposal.
- **Laboratory Personnel:** Properly label, store, document, and request disposal of samples.
- **QA/QC:** Reviews retention and disposal records. Audits procedures for compliance.

3. Procedure

1. Sample Labeling and Documentation

- Label each sample with unique identifier, date of receipt/collection, content description, and responsible person.
- Record all information in the Sample Logbook or LIMS.

2. Sample Storage

- Store samples in designated storage areas under specified conditions (e.g., temperature, light, humidity) as per SOPs or manufacturer recommendations.
- Restrict access to authorized personnel only.

3. Retention Period

- Retain samples for the period stipulated by relevant regulatory and company guidelines (see table below).

Sample Type	Retention Period	Storage Conditions
Raw Material	1 year after expiration/release	Ambient/cool storage
Finished Product	1 year after expiration	Ambient/cool storage
Stability Samples	According to protocol/SOP	As per required testing conditions

4. Chain of Custody

- Document any movement or transfer of samples using appropriate logs.
- Maintain traceability at all times.

5. Sample Disposal

- Identify samples eligible for disposal according to expired retention periods or as authorized by QA/QC.
- Document disposal date, method, and person responsible.
- Use environmentally responsible disposal methods, following local regulations for hazardous or biohazardous materials.

4. Documentation

- Maintain all records (labeling, storage, logbooks, disposal forms) for at least 3 years post-disposal, unless otherwise required.
- Ensure records are legible, stored securely, and accessible only to authorized personnel.

5. References

- Regulatory Guidelines (FDA, EMA, etc.)
- Company Quality Manual
- Environmental Health and Safety (EHS) Procedures

6. Revision History

Version	Date	Description of Change	Approved By
1.0	[Insert Date]	Initial Creation	[Approver Name]