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Sample Management

Overview

Purpose

This Standard Operating Procedure (SOP) addresses the following topics of managing samples:

- Receipt and processing
- Rejections
- Storage
- Transfers and analyst custody
- Shipping
- Disposal

Scope

This procedure applies to sample handling after they are received in ORS laboratories.

Note: *ORS laboratories do not routinely collect samples outside the laboratory. The Food and Drugs Administration (FDA) Investigations Operations Manual (IOM) outlines the field collection requirements and sampling plans.*

Contents

The table below lists the contents of this SOP.

Management of Samples

Overview

Contents

The table below lists the topic(s) in this section.

Roles, Personnel and Responsibilities

Laboratory Management

The Laboratory Management must

- extend an overall control of the samples in the laboratory, and
- ensure the training of the personnel in the proper handling, storage, accountability, and security of samples.

Sample Analysts

The Sample Analysts must

- document sample receipt, and
- maintain sample
  - accountability in FACTS
  - storage
  - disposal or intra-laboratory transfers, and
  - security within their areas

Sample Custodians

The Sample Custodians must

- document sample receipt
- maintain sample
  - accountability in FACTS
  - storage
  - disposal or intra-laboratory transfers, and
  - security within their areas.
- be responsible for the initial and final stages of sample storage and/or disposal.

Compliance Officers

The Compliance Officers – Compliance Branch of the Collecting Division must authorize disposition of samples.

Note: *In the case of non-FDA samples, the requesting or collecting organization authorizes disposition.*

Sample Management Process

Stages of sample management

The table below describes the stages of sample management.

Stage	Who	Does What
1	• Sample Analysts, or • Sample Custodians	• Receive the samples. • Process the sample receipt.
2	Sample Custodians	Store the samples appropriately.
3	Sample Analysts	Analyze the samples.
4	• Sample Analysts, or • Sample Custodians	Transfer the samples within the laboratory, when needed.
5	Compliance Officers	Approve sample disposition.
6	• Sample Analysts, or • Sample Custodians	Dispose of the samples.

Sample Receipt

FDA samples collection

Receive the samples for the analyzing laboratory in a designated area (i.e., sample processing room) as follows:

Stage	Who	Does What
1	Field Accomplishments and Compliance Tracking System (FACTS)	Associates a Collection Report (C/R) to the sample.
2	FACTS	Assigns, sequentially, a unique identification number which initiates sample tracking.

Reference: *Sample identification is described in the Investigations Operations Manual (IOM).*

Non-FDA samples collection

For non-agency samples (e.g., State or USDA) delivered to the laboratory, the following activities occur:

Stage	Who	Does What
1	FACTS	Generates the following: • A unique identification • A corresponding Collection Report
2	Laboratory	Does **one** of the following: • Initiates sample tracking. • Accepts the sample in FACTS to assign the unique identification number for the sample.

Samples submitted for storage only: non-FDA agencies

Ensure the following for samples from non-FDA agencies received for storage purposes only:

- Do not enter the samples into FACTS.
- Track them using the local procedures.
- The requesting or collecting agency's identification acts as the unique identifier.

Sample Processing

Acceptance criteria of samples

A sample should fulfill the following conditions for it to be accepted within the laboratory:

- No visible damage
- No leakage
- All seals intact

Handling physical damage

The table below describes guidelines to handle physical damages of samples received:

When there is a …	Then …
loss of sample due to incomplete or improper sealing: • Leakage of liquids from bottles • Loss of particulate material from containers • Improper sealing of bags	• the supervisor in the area of requested testing will consult with the collecting office to determine if any remaining sample can be salvaged for testing, and • if none of the sample can be salvaged, classify it is as a Class 5.
leakage	• contain the leak, and • notify the local Industrial Hygienist or Supervisor in accordance with the laboratory's local procedure.
damage or compromised sample: • Damaged • Contaminated, or • Integrity questioned	• the management notifies the collecting office verbally or electronically of the issue • the collecting office is consulted on the course of action to take • store the sample until further instructions are provided by the laboratory management in conjunction with the collector to continue processing the sample, and • document all communications.

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Sample Processing, Continued

Other guidelines

Ensure the following guidelines when receiving the samples:

- Laboratory Management and/or the Quality System Manager are the authorizing officials to determine whether samples not meeting required criteria for testing are rejected.
- Process the perishable or urgent priority samples received first. Notify the applicable section Supervisor or assigned analyst.
- Document the following in accordance with the SOP-000285 Sample Feedback Report Process:
  - Sample issues
  - Related Communications
  - Issue resolution

Other information to verify

The Sample Custodian verifies the following information along with the physical condition of the samples.

Information	Description
Analysis requested	If an analysis is not performed by the receiving lab, contact the management, or follow the local instructions to forward the sample to the correct analyzing laboratory
Presence of seal and seal integrity	Seals are not needed on all samples ***Reference:*** *See the IOM, Section 4 for sample identification requirements.*
Seal quotation, including date and signature or initials	Must be consistent with the electronic C/R
Shipping conditions	• Must be in accordance with the sample environmental/storage requirements • If not found acceptable, contact the supervisor for clarification

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Sample Processing, Continued

Sample receipt: procedure

Do as follows to receive the sample.

Note: *All records or documentation received with the sample (i.e. chain of custody forms from Office of Criminal Investigations) remain with the sample records throughout any transfers within the laboratory.*

Step	Action
1	• Observe the general condition of the arriving packages containing samples. • Record the following in FACTS: – Condition of the sample(s) – Acceptability of the sample ***Note:*** *If a sample is leaking, contain the leak. Notify the local Industrial Hygienist or Supervisor in accordance with the laboratory's local procedure.*
2	Compare each sample with the C/R for the following items: • Collector • Analyzing organization • Number of units • Collection date • Sample identification number • Matrix and product identification • Requested analyses • Storage conditions
3	Is the C/R and its sample incomplete? • If *yes*, notify a supervisor or analyst. (**Note:** If possible, the person receiving the sample shipment or Supervisor contacts the collecting officer to resolve immediate discrepancies.) • If *no*, process to step 4. ***Note:*** *Annotate the modifications or instructions in FACTS.*
4	Does the sample ID match the sample ID on the C/R? • If *yes*, proceed to step 6. • If *no*, hold the sample pending clarification from the collector.

Sample Storage

Samples awaiting analyses

Place the samples awaiting analyses in storage locations designated and designed to protect the integrity of the sample. Store the samples awaiting analyses as follows:

- The samples frozen, refrigerated or at room temperature in accordance with the instructions received with the sample, program requirements, or laboratory management
- The controlled drug substances in a separate locked area (i.e., safe) with limited access

Sample storage areas

The sample storage areas are designed to prevent contamination, cross contamination, or damage to the sample packaging and any seals. Each laboratory has a local procedure for monitoring the environmental conditions of sample storage areas.

Sample storage during analysis

Keep the samples kept in locked/limited access areas while in the analyst's possession.

If limited access storage is not available or practical within the testing lab area(s), return the sample to the Sample Custodian.

Sample Transfers

Within the laboratory

Ensure the following when transferring samples within the laboratory:

- **Chain of Custody:** Record the Chain of Custody for sample transfers between the Sample Custodian and analysts in FACTS. Documented them on the analytical worksheet.
- **Transfer between analysts:** Document the samples transferred between analysts
  - on the analytical worksheet, and
  - in FACTS.
- **Splitting samples:** When splitting the samples within the laboratory (i.e., a sample that requires an analysis by two or more different work areas),
  - perform the "In-House Split" operation within FACTS, and
  - create an assignment in FACTS.
- **Reserve sample portions:** Return all reserve portions of all samples to the Sample Custodian unless documented otherwise on the analytical worksheet and in FACTS.

Outside the laboratory

Ensure the following when transferring samples outside the laboratory:

- **Sample integrity and condition:** Ship samples ensuring sample integrity and condition.
- **Sample or its portions:** Enter the samples or portions of samples transferred outside the laboratory in FACTS. Document the sample that requires a portion to be sent elsewhere in FACTS by performing the "Sample Split" operation.
- **Information to document:** Document the following information for all samples or portions shipped:
  - What was provided and how much?
  - How was it prepared for delivery?
  - How was it identified and sealed?
  - A brief explanation as to why the sample or portion was sent
  - To whom was the sample or portion sent?
  - The date of shipment
- **Split samples between FDA/ORA:** For samples that are split between FDA/ORA laboratories, each examining laboratory handles and describes its portion of the sample as though it were an original analysis.

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Sample Transfers, Continued

Sample reserves

Ensure the following when handling sample reserves:

- Prepare the sample reserves and return them to the Sample Custodian upon completion of the analysis for storage or shipment. Document them on the worksheet and in FACTS.
- The Sample Custodian stores the reserve
  - in the designated storage area, and
  - under proper storage conditions that ensures its integrity.
- If a sample is depleted during analytical processes, record this on the worksheet and in FACTS.

Sample Disposition

Regulations

Dispose samples in accordance with the Federal, State, and local regulations.

Authorization to dispose

Authorization to dispose samples comes from any of the following through the FACTS-Sample Disposition Notice (SDN):

- Compliance Officer
- Laboratory Director, or
- Designated laboratory personnel

What is in-house disposition?

Under certain circumstances, in accordance with the laboratory procedure, the analyst may dispose of a sample. In FACTS, this is an in-house disposition of the sample reserve.

Guidelines for in-house disposition

Follow the guidelines below to perform the in-house disposition:

- Use a local procedure or program specific requirements to determine under what circumstances and conditions the analyst may destroy the reserve.
- The analyst documents the in-house destruction of the reserve sample in FACTS.
- Complete the disposition of the sample in a timely manner following the receipt of the disposition authorization in FACTS or by memorandum. Document the date of disposal in FACTS.

Destruction of reserve samples

The analyst may destroy the reserve samples when

- there is no reserve sample remaining because the entire sample was consumed during analysis
- the reserve sample is an import product with no action indicated (NAI) classification, and/ or
- there are perishable samples with NAI classification where the Supervisor has concurred with immediate destruction.

References

Overview

Contents

The table below lists the topics in this chapter.

Abbreviations

List of terms and their full forms

The table below provides the full forms of the abbreviated terms used within this SOP.

Term	Full Form
C/R	Collection Report
FACTS	Field Accomplishments and Compliance Tracking System
FDA	Food and Drug Administration
IOM	Investigations Operations Manual
NAI	No Action Indicated
ORA	Office of Regulatory Affairs
SDN	Sample Disposition Notice
SOP	Standard Operating Procedure
USDA	United States Department of Agriculture

Glossary

List of terms and definitions

The table below provides the definitions of the terms used within this SOP.

Term	Definition
FACTS	FDA's national operational database used to • manage field work assignments, and • record work results from assignment through compliance action
Sample accountability	A continuous record providing objective evidence that the sample's integrity has been preserved and demonstrates continuity of handling and chain of custody

Document and Records References

List of document references

The table below provides the list of documents this SOP refers to.

Document Code	Document Name
ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories, section 7.4
NA	AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017 August 2018
NA	FD&C Act Section 702(b)
NA	FDA Investigations Operations Manual (IOM), current revision
NA	Local sample storage area work instructions
NA	ORA Laboratory Manual, Volume III, Section 2, Chain of Custody – Sample Handling
SOP-000285	Sample Feedback Report Process

List of records

The list below provides the records this SOP refers to.

- Collection Report
- FDA Official Seal
- Analyst Worksheet
- Electronic records, such as FACTS
- Sample Feedback Report form

Formats and Attachments

Overview

Contents

The table below lists the topic(s) in this chapter.

Format 1: Not applicable

Format to use Not applicable.

Attachment 1: Not Applicable

Attachment to use	Not applicable

Document and Change History

Overview

Contents

The table below lists the topic in this chapter.

Document History

Document details

The table below lists the revision history for this SOP.

**: D: Draft, I: Initial, R: Revision*

Revision No.	Status (D/I/R)*	Date	Author Name and Title	Approving Official Name and Title
1.2	R	11/16/05	LMEB	LMEB
1.3	R	08/15/08	LMEB	LMEB
1.4	R	01/11/11	LMEB	LMEB
1.5	R	05/08/14	LMEB	LMEB
02	R	06/06/19	LMEB	LMEB

Change Details

List of changes

The table below provides the change history for this SOP.

Revision #	Change
1.2	In Document
1.3	In Document
1.4	In Document
1.5	In Document
02	Revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.