Sections in This Document

1. Purpose

This procedure addresses the topics of sample receipt and processing, sample rejections, sample storage, sample transfers and analyst custody, sample shipping, and sample disposal.

2. Scope

ORS laboratories do not routinely collect samples outside the laboratory. Field collection requirements and sampling plans are outlined in the FDA Investigations Operations Manual (IOM). This procedure applies to sample handling after they are received in ORS laboratories

3. Responsibility

A. Laboratory Management

1. Responsible for the overall control of samples in the Laboratory and ensuring personnel are trained in the proper handling, storage, accountability, and security of samples.

B. Sample Custodians and Analysts

1. Are responsible for documenting sample receipt, maintaining sample accountability in FACTS, storage, disposal or intra-laboratory transfers, and security of the samples within their areas.
2. Sample Custodian personnel are responsible for the initial and final stages of sample storage and/or disposal.

C. Compliance Officers

1. Compliance Officers of the Compliance Branch for the collecting division are responsible for authorizing disposition of samples. In the case of non-FDA samples, the requesting or collecting organization authorizes disposition.

4. Background

None

5. References

A. FDA Investigations Operations Manual (IOM), current revision

B. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, section 7.4.

C. 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.

D. FD&C Act Section 702(b)

E. SOP-000285 Sample Feedback Report Process

6. Procedure

6.1. Sample Receipt

6.1.1. Receipt of FDA Samples

A. Samples for the analyzing laboratory are received in a designated area (i.e. sample processing room).

B. Agency samples delivered to the laboratory must have an associated Collection Report (C/R) in the Field Accomplishments and Compliance Tracking System (FACTS). FACTS assigns, sequentially, a unique identification number which initiates sample tracking. Sample identification is described in the Investigations Operations Manual (IOM).

6.1.2. Other (Non-FDA) Samples:

For non-agency samples (e.g. State or USDA) delivered to the laboratory, unique identification and a corresponding Collection Report are generated in FACTS. The laboratory initiates sample tracking or accepts the sample in FACTS to assign the unique identification number for the sample.

6.1.3. Samples Submitted for Storage Only:

Samples from non-FDA agencies received for storage purposes only do not need to be entered into FACTS but are to be tracked using local procedures. The unique identifier would be the requesting or collecting agency's identification.

6.2. Sample Receipt and Processing:

A. Upon receipt of the sample the sample custodian or alternate observes the general condition of the arriving packages containing samples.

1. The sample custodian records the condition of the sample(s) and compares 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, and storage conditions.

2. If a collection report and its samples are received and found to be incomplete the sample custodian notifies a supervisor or analyst. If possible, the person receiving the sample shipment or Supervisor will contact the collecting officer to resolve immediate discrepancies.
3. Modifications or instructions are annotated in FACTS.
4. If the sample ID does not match the sample ID on the collection report, the sample is held pending clarification from the collector. If clarification cannot be satisfactorily obtained, the samples are stored temporarily or returned.
5. If the sample is rejected, the reason for rejection is documented in FACTS. The sample may be returned to the collector.
6. Any 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.

B. The sample custodian verifies other information such as:

1. If applicable, presence of seal and seal integrity (NOTE: Seals are not needed on all samples. See the IOM, Section 4 for sample identification requirements);
2. Seal quotation, including date and signature or initials are consistent with electronic C/R;
3. Analysis requested (If an analysis is not performed by the receiving lab, management is contacted, or local instructions are followed to forward the sample to the correct analyzing laboratory); and
4. Shipping conditions are in accordance with sample environmental/storage requirements (If not, the supervisor is contacted for clarification).

C. Sample condition and acceptability is checked and documented in FACTS

D. The following criteria determine the acceptance or rejection of samples:

1. physical condition of the sample container (e.g. visible damage, leakage, seals intact). If unacceptable, the collector is notified verbally or electronically by a Supervisor, analyst or Sample Custodian and the sample is classified as a Class 5.
2. NOTE: If a sample is leaking, contain the leak and notify the local Industrial Hygienist or Supervisor in accordance with the laboratory's local procedure.

3. For loss of sample due to incomplete or improper sealing (e.g. leakage of liquids from bottles, loss of particulate material from containers and 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. If none of the sample can be salvaged it is classified as a Class 5.
4. For samples that have been compromised (i.e. damaged, contaminated, or integrity questioned) the collecting office is notified verbally or electronically by management of the issue and consulted on the course of action to take. The sample is stored until further instructions are provided by laboratory management in conjunction with the collector in order to continue processing the sample. All communications are documented.

E. Laboratory Management and/or the Quality System Manager are the authorizing officials to determine whether samples not meeting required criteria for testing are rejected.

F. Acceptable samples are logged into FACTS. The following information at a minimum will be annotated: date received (FACTS field defaults to date entered), condition of container, shipping information, seal quotes, where (city and state), storage location, and any comments in the special handling instruction field.

G. Perishable or urgent priority samples received will be processed first and the applicable section Supervisor or assigned analyst is notified.

H. Sample issues, communications, and their resolution will be documented in accordance with SOP-000285 Sample Feedback Report Process.

6.3. Sample Storage

6.3.1. General

Samples awaiting analyses are placed in storage locations designated and designed to protect the integrity of the sample.

A. Samples are stored frozen, refrigerated or at room temperature in accordance with instructions received with the sample, Program requirements, or laboratory management. Controlled drug substances are stored in a separate locked area (i.e. safe) with limited access.

B. 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.

6.3.2. Sample Storage During Analysis

A. Samples are kept in locked/limited access areas while in the analyst's possession.

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

6.4. Sample Transfers

6.4.1. Within the Laboratory

A. Chain of Custody for sample transfers between the Sample Custodian and analysts are recorded in FACTS and documented on the analytical worksheet

B. Samples transferred between analysts are documented on the analytical worksheet and in FACTS.

C. When the splitting of samples within the laboratory is needed (i.e. a sample that requires an analysis by two or more different work areas), it is accomplished by performing the "In-House Split" operation within FACTS and creating an assignment in FACTS.

D. Reserve portions of all samples are returned to the Sample Custodian unless documented otherwise on the analytical worksheet and in FACTS.

6.4.2. Outside of the Laboratory

A. Samples are shipped to ensure sample integrity and condition.

B. Samples or portions of samples transferred outside the laboratory are entered and accomplished in FACTS. A sample, that requires a portion to be sent elsewhere must be documented in FACTS by performing the "Sample Split" operation.

C. The following information is documented for all samples or portions shipped: (1) what was provided and how much, (2) how it was prepared for delivery, (3) how it was identified and sealed, (4) a brief explanation as to why the sample or portion was sent, (5) to whom the sample or portion was sent, and (6) the date of shipment.

D. 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.

6.4.3. Sample Reserve Portions

A. Sample reserves are prepared and returned to the Sample Custodian upon completion of the analysis for storage or shipment and documented on the worksheet and in FACTS.

B. The Sample Custodian stores the reserve in the designated storage area and under proper storage conditions that ensures its integrity.

C. If sample is depleted during analytical processes, this is recorded on the worksheet and in FACTS.

6.4.4. Sample Disposition

A. Samples are disposed of in accordance with Federal, State and local regulations.

B. Authorization to dispose samples comes from the Compliance Officer, the Laboratory Director, or designated laboratory personnel through the FACTS-Sample Disposition Notice (SDN). Under certain circumstance 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.

C. If the in-house disposition is used, a local procedure or program specific requirements is used to determine what circumstances and conditions the analyst may destroy the reserve. Examples where reserve samples may be destroyed by the analyst are:

1. no reserve sample remains because the entire sample was consumed during analysis,
2. the reserve is an import product with no action indicated (NAI) classification or
3. perishable samples with NAI classification where the Supervisor has concurred with immediate destruction.

D. The analyst documents the in-house destruction of the reserve sample in FACTS.

E. Disposition of the sample is completed in a timely manner following receipt of the disposition authorization in FACTS or by memorandum. Date of disposal is documented in FACTS.

7. Glossary/ Definitions

A. FACTS - The Field Accomplishments and Compliance Tracking System (FACTS) is FDA's national operational database used to manage field work assignments, and record work results from assignment through compliance action.

B. Sample accountability – This is a continuous record providing objective evidence that the sample's integrity has been preserved and demonstrates continuity of handling and chain of custody.

8. Records

A. Collection Report

B. FDA Official Seal

C. Analyst Worksheet

D. Electronic records, such as FACTS

E. Sample Feedback Report form

9. Supporting Documents

Local sample storage area work instructions

ORA Laboratory Manual, Volume III, Section 2, Chain of Custody – Sample Handling.

10. Document History

Revision #	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	06/06/2019	LMEB	LMEB

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

11. Change History

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.

12. Attachments

None