ION LABS QUALITY FIRST	Standard Operating Procedure **Reserve Sample Handling, Storage, and Disposal – Raw Materials**	SOP Number D-304	Revision 4
		Effective Date (illegible)	Page Page 1 of 3
Written by/ Date (illegible)	Reviewed by/ Date (illegible)	Approved by/ Date (illegible)	
Title: Analytical Development Scientist	Title: Analytical Development Manager	Title: Quality Control Laboratory Director	

100 Purpose

This procedure defines requirements for the transfer of custody of raw material reserve samples to the QC Laboratory, as well as storage and disposal of reserve samples.

200 Scope

This procedure covers receiving raw material reserve samples, storage in climate monitored locations, disposal of reserve samples and the required documentation to track the process. This procedure applies to dietary, companion animal, cosmetic, and pharmaceutical raw material samples.

300 Responsibility

311 QC Sampling is responsible for transporting samples to the QC laboratory and logging the delivery process.

322 QC Laboratory Personnel are responsible for maintaining inventory and arranging disposal of reserve samples.

333 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.

344 It is the responsibility of QC Laboratory Management to keep the SOP current with latest Ion Labs practices.

400 Definitions

311 **Reserve Sample** – Representative samples of each lot or batch of API, excipients, packaging material, intermediates, or finished products which are kept for purpose of future reference.

322 **Dietary Active ingredient** – Any ingredient in a dietary supplement that is intended to supplement the diet, i.e. vitamins or minerals.

333 **Active Pharmaceutical Ingredient (API)** – Ingredient in a pharmaceutical or drug that is biologically active.

3.4 QC - Quality Control

3.5 QA - Quality Assurance

5.0 References

5.1 D-201, SOP, QC Laboratory Sample Log Book Recording

5.2 E-801, SOP, Return of Materials and Destruction of Non-Hazardous Waste Materials

5.3 E-801.0, SOP, Handling Regulated Chemicals

5.4 D-501, SOP, Stability Program for Finished Products

5.5 D-201-F1, Form, QC Laboratory Sample Log

5.6 21 CFR Part 211.170, Reserve samples for Drugs

6.0 Procedure

6.1 Reserve raw material samples will be collected for all dietary active ingredients associated with finished product batches, limited to vitamins and minerals only.

6.2 Per 21 CFR 211.170, raw material reserve samples will be collected for all active pharmaceutical ingredients (API's) used in drug products.

6.3 Reserve samples may be collected for all raw materials used in finished product batches, regardless of intended use, however, this is not a CFR requirement for drug excipients, dietary supplements, cosmetics, and companion animal products.

6.4 Liquid raw materials are not collected and retained as reserve samples, unless the liquid is a drug product API.

6.5 Reserve samples are delivered to the QC laboratory and the required information is logged into Form D-201-F1 QC Laboratory Sample Log. For instruction on the information needed and logging in reserve samples, refer to SOP D-201 QC Laboratory Sample Log Book Recording.

6.6 QC Laboratory Personnel will review the QC log entry and verify accuracy of the information before accepting. Acceptance of the reserve sample is acknowledged by an entry from QC Laboratory Personnel onto the QC Laboratory Sample Log as per SOP D-201.

6.7 Reserve Sample Storage

6.7.1 Raw material reserve samples are stored in a QC Laboratory designated location.

6.7.2 All reserve samples are stored in designated rooms with environments monitored as per SOP D-501 Stability Program for Dietary Supplements and Cosmetics.

6.7.3 Raw material reserve sample storage containers will be identified in such a way that indicates the time in which the samples shall be ready for destruction. For example, a raw material is located in the fifth box identified for destruction in Quarter 1 of 2025. The storage container should be labeled as "Q1-25-5" or as applicable for indication.

6.8 Disposal

6.8.1 All API's must be maintained for at least one year past the expiration date of the last lot of drug product containing the API. Ion Laboratories will maintain API's for 7 years after receipt.

6.8.2 All dietary active ingredient raw material reserve samples must be maintained for five years from date of receipt, after which, they may be discarded following SOP E-801 Return of Materials and Destruction of Non-Hazardous Waste Materials.

6.8.3 Controlled Substances are to be disposed of as per SOP E-801.0 Handling Regulated Chemicals.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New	-	-
1	02/06/13	Added specific information to be logged, added QA as responsible for compliance with Sop, updated format	13-057	B. Johns
2	01/22/15	Changed Title. Remove reference of obsolete SOP D-301. Referenced E-801, D-404 and D-501. Improved clarity. Biennial Review.	15-0093	B. Johns
3	04/04/17	Updated to include cosmetics and pharmaceuticals. Added E-801.0 for regulated substances. Refocus SOP to cover only raw materials.	17-1141	B. Johns
4	07/20/20	Update Responsibilities. Update References	CC-20-05113	S. Sassman