ION LABS QUALITY FIRST	Standard Operating Procedure Finished Product Reserve Samples	SOP Number D-404	Revision 8
		Effective Date 12/17/19	Page Page 1 of 3

Written by/ Date	Reviewed by/ Date	Approved by/ Date
SSS 11/27/19	12-02-19	12-07-19
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1.0 Purpose

The purpose of this SOP is to define the process for the sampling, storage, and disposal of finished product reserve samples. This procedure also defines the process and parameters to help ensure an appropriate representative sample of each batch of finished product is reserved in sufficient quantities and stored in the appropriate environment.

2.0 Scope

This procedure applies to all products manufactured at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of QC to obtain samples of finished product and deliver the samples to the QC Laboratory.

3.2 It is the responsibility of the QC Laboratory to store and maintain reserve samples.

4.0 Definitions

4.1 **Reserve Sample** – Finished product stored in its finished product container if bottled or blister packed, or stored in a suitably sized container for products shipped in bulk packages.

4.2 **QC** – Quality Control

5.0 References

5.1 E-702, SOP, Finished Product Sampling Procedure

5.2 D-201-F1, Form, QC Laboratory Sample Log Book

5.3 E-801.0, SOP, Handling Regulated Chemicals

5.4 D-105, SOP, Out of Specification / Out of Trend Investigation

5.5 21 CFR 111.83, What are the requirements for reserve samples? *(Dietary Supplements)*

5.6 21 CFR 111.465, What requirements apply to holding reserve samples of dietary supplements?

5.7 21 CFR 211.170, Reserve samples *(OTC Pharmaceuticals)*

5.8 21 CFR 211.137, Expiration dating *(OTC Pharmaceuticals)*

6.0 Procedure

6.1 Sampling

6.1.1 QC inspectors will select finished product packages and bulk product from each finished product batch using SOP E-702 Finished Product Sampling Procedure.

6.1.2 QC inspectors will deliver samples to the QC Laboratory and log them onto Form D-201-F1 QC Laboratory Sample Log Book.

6.1.3 Reserve Samples will be held in the same container/closure in which the packaged and labeled finished product is distributed.

6.1.4 The reserve sample consists of at least twice the quantity necessary to perform all the required tests.

6.1.5 Deviation from the default reserve sampling procedure will occur in the following instance:

6.1.5.1 The default number of six reserve samples can be reduced to a number no less than three bottles when sufficient dosages exist in a reserve sample to justify a reduced number of packages. The reserve quantity must meet the requirements of 21 CFR 111.83 or 21 CFR 211.170.

6.1.5.2 Justification for reduced reserve sampling will be listed in the exemption section of the product profile.

6.2 Storage

6.2.1 Reserve samples are to be stored at monitored room temperature and humidity conditions.

6.2.2 Reserve samples are to be stored and maintained in a manner that allows for easy retrieval.

6.2.3 Specific location of reserve samples are logged into an excel spreadsheet and tracked by box number.

6.2.3.1 Reserve samples may be stored in 12" X 12" X 24" brown boxes with the inventory listed on the outside of the box.

6.2.3.2 Individual reserve samples should only be removed from the program if justified, i.e. customer complaint investigation.

6.2.3.3 If a reserve sample is removed from the program then a notation into the spreadsheet should be made for accountability purposes.

6.3 Inspection- Drug and OTC products only

6.3.1 All Finished Product Drug and/ or OTC reserve samples will have an annual inspection performed.

6.3.2 Each FP lot will be visually examined for any sign of deterioration.

6.3.3 The results of the inspection will be recorded and maintained with other stability data on the drug product.

6.3.4 If product deterioration is observed then an investigation shall be performed per SOP D-105.

6.4 Disposal

6.4.1 Finished Product samples are reserved for one year past the shelf life date (if shelf life dating is used), or for three years from the date of manufacture for each batch of finished product that does not have an expiration date assigned.

6.4.2 During storage, any evidence of reserve sample deterioration should be investigated. The results of the examination will be recorded and maintained with other stability data if applicable.

6.4.3 After the reserve period, reserve samples are identified and removed the month following reserve expiration, or as time allows, using safe disposal practices.

6.4.3.1 Product containing listed substances will be disposed of as per SOP E-801.0 Handling Regulated Chemicals.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/16/10	New	-	-
1	07/29/10	Organized SOP.	-	-
2	03/27/13	Updated SOP to new format.	-	-
3	06/06/13	Changed SOP number.	-	-
4	12/12/13	Changed SOP title. Edited SOP content.	13-1153	M. Wienke
5	11/26/14	Added section 6.1.3 and 6.1.4. Updated SOP format and section 6.3.1, 6.3.2	14-0943	V. Iltcheva
6	12/14/16	Update SOP to include OTC finished products. Referenced 211 series CFR's. Added D-102.0, D-105 and D-801.0 references.	16-1142	B. Johns
7	04/07/17	Updated storage practices for new facility.	17-0397	B. Johns
8	11/27/19	Revised for reserve sample clarification. Added Inspection of Drug and OTC products.	19-0885	J. Sassman