



QUALITY ASSURANCE AND REGULATORY AFFAIRS DEPARTMENT

TITLE: SAMPLE RETENTION	Number OPR 072	Page 1/3
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Issue Date: (D/M/Y)	Effective Date : (D/M/Y)	Supersedes Date: (D/M/Y)
		NEW

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I. PURPOSE

The purpose of this document is to describe the Quality Assurance requirements to ensure appropriate storage and managing of reserved samples.

II. SCOPE

This document applies to all corporate manufacturing sites, importers (and/or distribution centers) that retain samples to fulfill the current regulatory requirements.

III. BACKGROUND

Under the Regulations, a representative sample of every batch of the packaged/labeled health product must be retained under storage conditions for a period of one (1) year after the expiration date, which indicated on the label of the product.

IV. RESPONSIBILITIES

It is the responsibility of the Quality Assurance Manager to ensure that appropriate systems are in place to retain representative samples of manufactured or imported health products, and the samples are stored under indicated conditions for one year past the shelf life date.

V. DEFINITIONS

Label:

Include any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, NHP, device or package.

Tight Container

A tight container protects the contents from contamination by extraneous liquids, solids, and vapor, or from loss of the article, (such as evaporation) under the ordinary or customary conditions of handling, shipment, storage, and distribution. This includes a well-closed container and tight re-closure.

Package:

Includes any material in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed.

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VI. REQUIREMENTS**A. TYPES OF REPRESENTATIVE SAMPLES MUST RETAINED**

The representative samples must include:

1. Representative samples of each unique lot of components, packaging, and labels to determine whether the components, packaging, and labels meet specifications
2. Representative samples of each manufactured finished batches before releasing for distribution to verify that the finished batch of product meets product specifications
3. Representative samples of each unique shipment, and of each unique lot within each unique shipment, of product that received for packaging or labeling (and for distribution rather than for return to the supplier) to determine whether the received product meets specifications
4. Representative samples of each lot of packaged and labeled product to determine whether the packaging and labeling of the finished packaged and labeled product meet specifications

B. REQUIREMENTS FOR RESERVE SAMPLES

The reserve samples must:

1. Be held using the same container-closure system, in which the packaged and labeled product is distributed,
2. Be identified with the batch, lot, or control number;
3. Be retained for one year past the shelf life date (if shelf life dating is used), or for two years from the date of distribution of the last batch of product and
4. Consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the product meets product specifications.
5. And conform to the conditions set out in Part 3: Good Manufacturing (Practices Lot or Batch Samples Section 61).

C. STORAGE

1. The warehouse storage condition shall be capable of meeting the ingredients and materials storage requirements.
2. Warehouse storage is to be inside storage wherever temperature conditions are specified.
3. Warehouse temperature shall be well controlled and monitored
4. Inside storage is, minimally, a roofed building protected from rodent and insect infestation with provisions to protect material against external environmental conditions (freezing or excessive heat).
5. Labeled storage conditions should be evaluated against corporate criteria and the established appropriate storage conditions (e.g., suppliers' labels).

NOTES:

1. Room temperatures shall be monitored and recorded each day
2. Notify immediate supervisor for temperatures that out of range.
3. Document any out of range readings and indicate the corrective action taken.

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D. PROCEDURE

1. Each batch is placed into an individual plastic bag and sealed.
2. A label (see table below) is prepared for each box identifying the internal tracking #, product name and strength, Lot/Batch No., and disposal month and year.
3. The bag(s) are filed according to the disposal month and year and stored under the required storage conditions in the boxes on the shelves in the storage room.
4. Once the sample has reached its disposal date, which is one year after the expiry date the sample removed from the shelves and destroyed.

Disposal Date	
Internal Tracking #	
Lot/Batch No	
Product Name	

VII. DOCUMENT INFORMATION**A. ATTACHMENTS**

None

B. DESCRIPTION OF CHANGE

New Procedure

VIII. DISTRIBUTION

Corporate Key Contacts

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