
	Standard Operating Procedure Finished Product Expiration Dating		SOP Number C-706	Revision 4
			Effective Date 01.17.20	Page Page 1 of 3
Written by/ Date A5 01/16/20		Reviewed by/ Date  01/17/20		Approved by/ Date 
Title: Analytical Development Scientist		Title: R&D Manager		Title: QC Laboratory Director

1.0 Purpose

The purpose of this SOP is to describe the processes involved in selection and verification of expiration dates for finished products. This is done to assure that products manufactured at ION Labs, Inc. meet applicable standards of identity, strength, quality and purity at the time of use.

2.0 Scope

This procedure applies to all finished products manufactured at Ion Labs which have an expiration date printed on the label.

3.0 Responsibility

- 3.1 It is the responsibility of R&D to assign an expiration dates based on standard overages and seek expert advice when no standard overage is assigned.
- 3.2 It is the responsibility of R&D in conjunction with QC Laboratory Management to formulate the product to meet shelf life expectations.
- 3.3 It is the responsibility of DC to track and log batches that require stability testing.
- 3.4 It is the responsibility of the QC Laboratory Management to execute a stability plan for the batches tracked for stability by DC.

4.0 Definitions

- 4.1 **Controlled Room Temperature** - A temperature maintained thermostatically that brackets the usual and customary working environment of 20°C to 25°C (68°F to 77°F) that results in a mean kinetic temperature calculated to be not more than 25°C and that allows for minor fluctuations between 15°C and 30°C (59°F and 86°F) that are experienced in pharmacies, hospitals, and warehouses.
- 4.2 **QC** = Quality Control
- 4.3 **DC** = Document Control
- 4.4 **CofA** = Certificate of Analysis
- 4.5 **SOP** = Standard Operating Procedure

4.6 R&D = Research and Development

5.0 References

5.1 C-104, SOP, Master Batch Record and Issuance of Batch Production Record

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

5.3 D-902, SOP, Establishment of Specifications

5.4 E-702, SOP, Finished Product Sampling Procedure

6.0 Procedure

4.1 During the quote process R&D selects an expiration date based on the stability characteristics of the formulation and the customer's specifications.

4.2 The stability characteristics of a formulation may be based on one or more of the following:

4.2.1 Previous stability data for similar formulations.

4.2.2 Accelerated stability data for the current formulation.

4.2.3 Scientific literature which examines the stability of specific ingredients or individual analytes present in the formulation.

4.3 The excess amount of any component in a formulation relative to the label claim for that component (the overage) is determined based on:

4.3.1 Known stability characteristics of the component. For example, ascorbic acid is known to be inherently unstable, therefore an overage must be added to ensure that the product will meet specification throughout its life cycle.

4.3.2 The finished product specification for the component. For example, if the specification is NLT 100% of label claim, an overage should be added to ensure that the component passes specification without regard to stability.

4.4 If product stability is unknown and the customer has no specific requirements, the default is two years.

4.5 Once the quote is accepted and the customer places an order, a product profile is generated in accordance with D-902 Establishment of Specifications which contains the shelf life and testing requirements.

4.6 Stability batches are identified by DC as per SOP C-104 Master Batch Record and Issuance of Batch Production Record.

- 477 Stability samples are delivered to the QC Laboratory as outlined in SOP E-702 Finished Product Sampling Procedure.
- 488 QC Laboratory Management reviews the corresponding finished product profile and generates a stability protocol based on the guidelines of D-501 Stability Program for Finished Products with the testing and specifications outlined in the respective product profile.
- 499 QC Laboratory Management prepares a stability trend card for trending the stability test results at each time interval according to D-501 Stability Program for Finished Products.
- 4100 Once stability testing is complete, a second verification check is recorded in the product stability protocol by QC.
- 4111 DC stores and maintains the completed product stability protocols with accompanying trend cards for all required products.
- 4112 An expiration date is considered verified after stability testing for the first three lots has been completed successfully as outlined in the corresponding stability protocol.

7.00 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/20/10	New	-	-
1	02/28/13	Changed the SOP format. SOP updated.	13-141	R. Howard
2	03/09/15	Biennial review. Updated SOP format. Revision 1 obsolete. New procedure written for raw material and finished product (Dietary Supplements). New Title.	15-0163	B. Johns
3	04/04/17	Sourced D-501 directly, for requirements to establish expiration dating on finished products. Changed title to include Cosmetics.	17-0349	B. Johns
4	03/04/20	Update References, Purpose, and Scope. Remove raw material expiration dating since this is covered in D-901. Combine D-706 and D-706.0 since the process is similar for dietary and drug.	20-0280	S. Sassman