1.0 Purpose

The purpose of this procedure is to give guidelines on expiration dating and labeling of laboratory chemicals, reagents, and media used in the QC Laboratory. This procedure will also define storage conditions for various chemical classes and give guidelines on logging the chemical inventory.

2.0 Scope

This procedure applies to all dry chemicals, organic solvents, prepared reagents and buffers, and microbiological media for intended use in QC Laboratory testing.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Analysts to follow this procedure.

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

3.3 It is the responsibility of QC Laboratory Management to keep this procedure up to date with current practices.

4.0 Definitions

4.1 **Reagent** – a compound or mixture added to a system to cause a chemical reaction or test if a reaction occurs

4.2 **Buffer** – a solution containing either a weak acid and its salt or a weak base and its salt,

which is resistant to changes in pH

4.3 **Solvent** – the component of a solution that is present in the greatest amount. It is the substance in which the solute is dissolved.

4.4 **SDS** – Safety Data Sheet

4.5 **QC** – Quality Control

4.6 **Media** – a mixture of substances that promotes and supports the growth and differentiation of microorganisms

4.7 **CofA** – Certificate of Analysis

4.8 **PQV** – Process Quality Verification

5.0 References

5.1 D-106, SOP, Analytical Standards

5.2 USP <1117>, Pharmacopeial Monograph, Microbiological Best Laboratory Practices

5.3 D-602-F1, Form, Microbiology Inventory Log

5.4 A-106, SOP, Documentation Guidelines for cGMP Records

5.5 C-501, SOP, Document Control Procedure

5.6 C-502, SOP, Record Storage, Retention, and Destruction

6.0 Procedure

6.1 General

6.1.1 Chemicals and microbiology media are delivered to the laboratory by warehouse receiving.

6.1.2 Warehouse receiving lists are used to verify inventory of received materials before taking custody.

6.1.3 Chemicals or media are received by QC Laboratory Management or designee and stored in the correct location.

6.2 Chemicals and Media Labeling

6.2.1 All chemicals and powder media received into the QC laboratory will be labeled with the following information:

6.2.1.1 Date of Receipt and Receipt Expiration Date

6.2.1.2 Date Opened and Opened Expiration Date

6.2.2 Commercially pre-made media received into the QC laboratory will be labeled with quarantine stickers, to indicate media verification is needed before use.

6.3 Solution Preparation Labeling

6.3.1 It is the expectation that all laboratory preparations can be traced back to the notebook or document in which the preparation occurred.

6.3.2 All solutions prepared in the laboratory will be clearly labeled with the following information (the UNIX method)

6.3.2.1 **U** – Unique identifier name (ex – D-XXX Standard, Batch/Lot #, Sample 1)

6.3.2.2 **N** – Notebook number and page number (ex – NB 98-112)

6.3.2.3 **I** – Initial and date of the analyst who prepared the solution

6.3.2.4 **X** – Expiration date of solution preparation

6.4 Expiration Dates

6.4.1 Expiration dates defined below should not exceed a manufacturer's expiration date for any reagent/solution. The manufacturer's CofA will be evaluated upon receipt per section 6.2.

6.4.2 Reference Standard Expiration Dates

6.4.2.1 Analytical Reference Standards – refer to SOP D-106 Analytical Standards.

6.4.3 Expiry Dating of Laboratory Chemicals, Solutions, and Microbiology Media

Sample/Solution Type	**Expiration Date as Received**	**Expiration Date once opened (not to exceed received expiration date)**
Dry Chemicals	5 years	2 years
Organic Solvents, i.e. methanol, ACN, IPA, etc.	2 years	1 year
USP Test Solutions (TS) (purchased)	2 years	1 year
pH Buffers (used for calibration of pH meter)	1 year	6 months
Acids < 1N, purchased	1 year	6 months
Acids ≥ 1N, purchased	2 years	1 year
Bases < 1N, purchased[1]	1 year	6 months
Bases ≤ 1N, purchased[1]	2 years	1 year
Volumetric Solutions[2]	1 year	6 months
Acids/ Bases < 1N, prepared[1]	3 months	[redacted]
Acids/ Bases ≥ 1N, prepared[1]	6 months	
Mobile Phases/ Diluents < 10% organic	1 month	
Mobile Phases/ Diluents ≥ 10% organic	3 months	
Buffer Solutions	1 month	
USP Test Solutions (TS) (prepared)	1 year (unless otherwise specified by USP)	
Sample/ Standard Preparations[3]	1 day unless otherwise specified in test method	
Organic Solvents (100%) used as Mobile Phase on HPLC	3 months	
Microbiological Media (Powder)	5 years	2 years
Microbiologic Media Prepared In-House	[redacted]	30 days

1. Certain bases will degrade when exposed to air and may require a shorter expiration date.
2. The expiration dates for volumetric solutions may be extended if the solution is re-standardized per the USP.
3. For example, samples/ standards prepared on Monday do not expire until midnight on Tuesday.

7.0 Inventory Reagent List

7.1 The laboratory shall keep an updated inventory list of all reagents and chemicals used for testing. Microbiology will use Form D-602-F1 Microbiology Inventory Log.

7.2 This list will include, at minimum, reagent name, vendor, lot number, grade (if applicable), receipt date, and expiration date.

7.3 Upon receipt into the QC laboratory, all reagents will be stickered as previously noted and entered into the inventory reagent list.

7.4 This list will be easily produced at all times and for any audit requests.

8.0 Documentation Requirements

8.1 A PQV check must be performed for each completed page of form D-602-F1 Microbiology Inventory Log as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

8.2 All documentation will be distributed and maintained as outlined in SOP C-501 Document Control and SOP C-502 Record Storage, Retention, and Destruction.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New procedure.	-	-
1	01/24/12	Updated format.	-	-
2	02/18/13	Defined logging procedures for standards, expanded on MSDS, adjusted parameters for expiration	-	-
3	10/24/13	Removed logging procedures for standards, reorganized logging system for chemical inventory, added form D-602-F1, expanded chemical storage areas, increased detail for determining expiration date, added certification procedure for certain expired chemicals, changed SOP title	13-952	B. Johns
4	06/15/16	Biennial review: Updated SOP Format.	16-0205	J. Maignan
5	04/19/17	Updated SOP to expand recertification of laboratory chemicals. Expanded criteria for justifying shelf life of reagents and media.	17-0440	B. Johns
6	09/03/19	Updated SOP to align with current laboratory and industry practices.	19-0599	I. Garrett
7	03/28/22	Updated to add the requirement of a laboratory inventory reagent list, per ISO 17025.	CC-22-0141	J. Sassman
8	09/14/22	Updated with microbiological media inventory.	CC-22-0255	G. Shaw
9	06/05/24	Updated to reflect current practices	CC-24-0243	A. Perez

ION Nutritional Labs	Microbiology Inventory Log		
	Form: D-602-F1	CCR No. CC-24-0243	Revision: 2

Logbook Number: _____

Medium or Supply Name	Source / Cat#	Lot#	Expiration Date	Quantity Ordered	Quantity Received	Receipt Date/Analyst	Validation Required (√)

PQV _____