Biopharmaceutical Development Program

Standard Operating Procedure

Title: Solutions Used in Process Analytics

SOP Number: 22702 **Revision Number: 02**

Supersedes: Revision 01 **Effective Date: APR 18 2011**

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 Purpose

This procedure describes the methods to prepare and document test solutions.

2.0 Scope

This Standard Operating Procedure applies to Process Analytics (PA) personnel who prepare solutions used for testing.

3.0 Authority and Responsibility

3.1 The Director, PA has the authority to define this procedure.

3.2 The Supervisor of PA is responsible for assignment of this procedure and for reviewing results for accuracy.

3.3 PA Laboratory personnel are responsible for the performance of this procedure.

- PA Laboratory personnel must wear gloves, safety glasses, and protective clothing while preparing and working with all the solutions in this procedure.

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- Avoid breathing vapors and skin contact with Image Development Reagents.
- Read and understand associated Material Safety Data Sheets (MSDS) for this procedure, and dispose of materials and samples per the appropriate procedure.

3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Procedure

4.1 General Preparation

Note: This procedure may be used in conjunction with other assay procedures; however, it will not supersede other assay procedures already approved that contain detailed specific instructions for solution preparation and labeling.

4.1.1 Volumetric apparatus, such as volumetric flasks, transfer and measuring pipets, and burets, used for the preparation of solutions must meet or exceed the standards of accuracy set by the National Institute of Standards and Technology (NIST) Class A. Although most volumetric apparatus are calibrated at 20ºC, the temperature generally found in the laboratory is closer to the 22-25ºC range. This discrepancy is inconsequential provided the room temperature is reasonably constant (see Current USP <31>).

4.1.2 Reagents are substances used either by themselves or as constituents of solutions. Reagents required in tests and assays must meet or exceed the American Chemical Society (ACS) specifications, whenever possible. Where no such specifications exist, use a suitable grade.

4.1.3 Indicators are reagents used to determine the specified endpoint in a chemical reaction, to measure hydrogen-ion concentration (pH), or to show that a desired change in pH has occurred.

4.1.4 Make solutions using the appropriate glassware or plasticware. Clean and rinse all containers and volumetric apparatus, if appropriate, before use. Water used in the preparation of solutions must meet or exceed Current USP Purified Water specifications.

4.2 Calculations for Solution Preparation

4.2.1 Molarity Calculations

Molarity = The weight of the material in grams ÷ (the molecular weight of the compound x the volume in liters).

4.2.2 Normality Calculations

Normality = (The weight in grams x the number of electrons changing in the reaction) ÷ (the molecular weight of the compound x the volume in liters).

Note: For normality, it is best to reference a handbook like the "CRC Handbook of Chemistry and Physics" for the number of electrons changing in the reactions.

4.2.3 Concentrations of Common Acids and Bases: These values are approximate and are acceptable for most test solutions.

	Percent by Weight	Density	Molarity
Acetic acid	99.5%	l.05	17.5
Ammonium hydroxide	27% (NH_3)	0.90	14.5
Hydrochloric acid	37%	1.18	12.1
Nitric acid	70%	1.41	15.9
Phosphoric acid	85%	1.69	14.8
Sulfuric acid	95.5%	1.83	18.0

4.3 Container Identification of Laboratory Solutions

All solutions must have labels affixed to them. Place the following information on the label. An example label is shown in Attachment 2. Other labels can be used (to accommodate the container size and shape) as long as all pertinent information is captured.

4.3.1 The name of the solution as stated in the procedure (Example: 0.1N Hydrochloric Acid).

4.3.2 The log number/lot number of the solution.

4.3.2.1 The log number is assigned sequentially. The format of this number is: logbook number - date (MMDDYY) – page number – page entry.

4.3.2.2 For example, 10-041007-45-2 would be the log number/lot number, the number of the logbook is 10, the date is April 10, the year is 2007, the page number is 45, and the entry on that page is 2.

4.3.2.3 This log number is used as the lot number when a stock solution is used to prepare diluted working solutions.

4.3.3 The concentration of the solution made, if applicable.

4.3.4 The pH of the solution, if applicable.

4.3.5 The amount of solution made.

4.3.6 The initials of the person preparing the solution and the date prepared.

4.3.7 The storage conditions of the solution as stated in **SOP 21902, *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials***.

4.3.8 The expiration date of the solution. See Section 5.6.

4.3.9 If using the example label shown in Attachment 2, N/A blanks that are not filled out and initial and date.

5.0 Documentation – Permanent Records for Laboratory Solutions

Logbooks made up of multiple copies of Form 22702-01 are maintained in each PA lab, for the solution with the following information. The attached form contains space for the necessary information to record when making up solutions, but the format may be modified as needed. Be sure that the pages are bound in a logbook and the pages are numbered.

5.1 Log number of the solution (See 4.3.1.1).

5.2 The storage conditions of the solution as stated in **SOP 21902, *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials***.

5.3 The name of the solution as stated in the procedure.

5.4 A list of the materials used to produce the solution. This will include:

5.4.1 Reagent name.

5.4.2 Vendor/BDP Lot Number.

5.4.3 Vendor lot number.

5.4.4 Expiration Date of Reagent.

5.4.5 Amount used (Include Units).

5.4.6 Balance number (if applicable).

Note: For solutions prepared in the laboratory, the laboratory is considered the vendor.

5.5 Calculations

5.6 The assigned expiration date.

5.6.1 Expiration dates shall be based on literature references, or the expiration date shall be assigned using the expiration date of the component used to make the solution that expires first.

5.6.2 Only **unexpired** components shall be used.

5.6.3 Defined expiration dates in the procedures shall be used when available.

5.6.4 All solutions will receive a log number/lot number to provide traceability to the reagents.

5.7 The final volume of the solution.

5.8 The name of the person making the solution.

5.9 The date the solution was made.

6.0 Storage of Prepared Solutions

Store each solution in a manner to preserve its integrity. For example, refer to the appropriate SOP or contact the Supervisor.

7.0 References and Related Documents

7.1 **SOP 21902** *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials*

7.2 Molarity of Commonly Used Acids and Bases http://poohbah.cem.msu.edu/courses/cem262/AcidBaseMolarity.html.

8.0 Attachments

8.1 **Attachment 1** Form 22702-01, Process Analytic Solution Log

8.2 **Attachment 2** Solution Label

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

Attachment 1

NCI-Frederick
Form No.: 22702-01
SOP No.: 22702
Revision 02:

Process Analytic Solution Log

Log Number: _____ Storage Conditions: _____

Solution Name: _____

Reagent Name	Vendor/BDP Lot No.	Vendor Lot No.:	Expiration Date	Amount Used	Balance No.

Calculations: _____

_____

Expiration Date: _____ Final Volume: _____

Preparer: _____ Date Prepared: _____

_____

Log number: _____ Storage Conditions: _____

Solution Name: _____

Reagent Name	Vendor/BDP Lot No.	Vendor Lot No.:	Expiration Date	Amount Used	Balance No.

Calculations: _____

_____

Expiration Date: _____ Final Volume: _____

Preparer: _____ Date Prepared: _____

Reviewed By: _____ Date: _____

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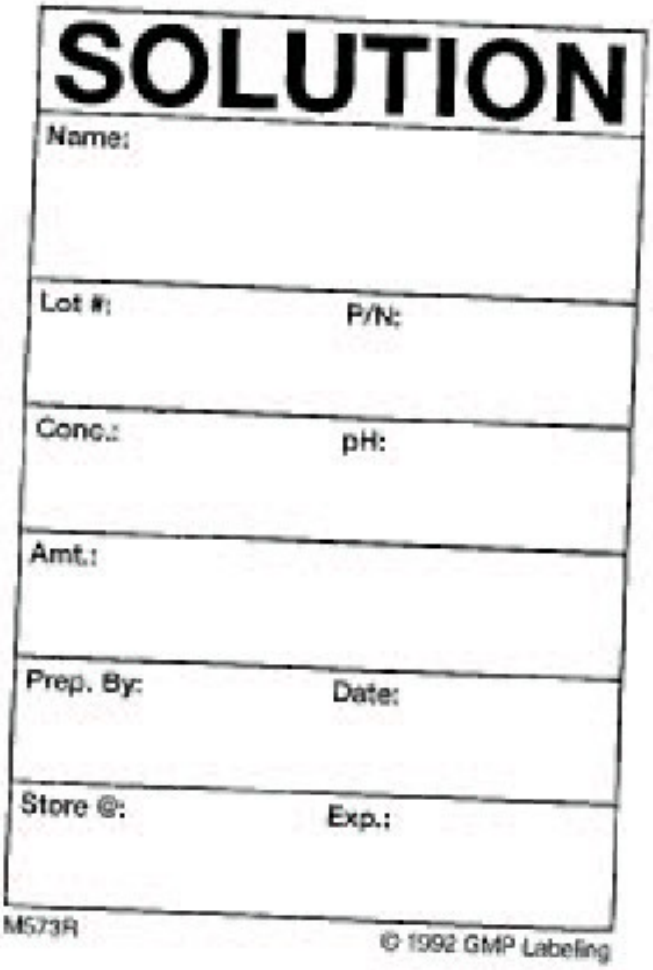
Attachment 2
Solution Label



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