SOP Title: **Solutions Used in Process Analytics**
SOP Number: **22702**
Revision: **04**

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1. PURPOSE

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

2. SCOPE

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

3. RESPONSIBILITIES

3.1 Director / PA/QC

- Defines the procedure.

3.2 Supervisor / PA/QC

- Assigns use and training for this procedure.
- Reviews the results.

3.3 PA/QC Laboratory personnel

- Performs this procedure.
- Follows all safety requirements, wears gloves, safety glasses and protective clothing.
- Understands associated Material Safety Data Sheets (MSDS).
- Avoids breathing vapors and skin contact with Image Development Reagents.

3.4 Biopharmaceutical Quality Assurance (BQA)

- Provides Quality oversight.

4. 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.

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 20°C, the temperature generally found in the laboratory is closer to the 22°-25°C range. This discrepancy is inconsequential provided the room temperature is reasonably constant (see Current USP <31>).

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.

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.

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

Molarity Calculations

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

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.

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

Acid or Base	Percent by Weight	Density	Molarity
Acetic acid	99.5%	1.05	17.4
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 Label for Laboratory Solutions

All solutions must have labels affixed to them. Place the following information on the label. An example label is shown in **Attachment 1**. Other labels can be used (to accommodate the container size and shape) as long as all pertinent information is captured.

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

The lot number of the solution.

4.3.1.1 The solution lot number is assigned sequentially and is a unique code determined by the logbook number, the page number, and the page entry number. Each logbook page is formatted to record two solutions (entries 1 or 2). .

4.3.1.2 The format of this number is: logbook number - page number – page entry. For example, EL-2016-0010-45-2 would be the lot number for a solution if the number of the logbook is EL-2016-0010, the page number is 45, and it is entry 2 on that page.

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

The concentration of the solution made, if applicable.

The pH of the solution, if applicable.

The amount of solution made.

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

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

The expiration date of the solution. See Section 5.6.

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

5. DOCUMENTATION AND RECORDS

Solution Logbooks are considered equipment logs, issued and handled according to **SOP 21531 Equipment Logs**. Solution logbooks are made up of multiple copies of **Form 22702-01** with each page numbered sequentially and bound in a logbook. These logbooks are maintained in each PA/QC lab. **Form 22702-01** contains space for the necessary information to record when making up solutions, but the format may be modified as needed. The entries in the solution logbook have designated spaces for the following information:

5.1 Log number of the solution (See 4.3.2).

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:

- Reagent name.
- Vendor/BDP Lot Number.
- Vendor lot number.
- Expiration Date of Reagent (if applicable).
- Amount used (Include Units).
- 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 dates.

Expiration dates are based on literature references, defined expiration dates in other BDP procedures are used when available or the expiration date is assigned using the expiration date of the component used to make the solution that expires first.

Only **unexpired** components are used for GMP testing.

R&D solutions may be made using expired components and "R&D Only" is to be indicated on both the solution label and in the log entry.

The solution lot number provides 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. STORAGE

Store each solution in a manner to preserve its integrity. Refer to the appropriate SOP or contact the Supervisor.

7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21531	Equipment Logs
21902	Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials
22702-01	Process Analytic Solution Log
	Molarity of Commonly Used Acids and Bases http://www.sigmaaldrich.com/chemistry/stockroom-reagents/learning-center/technical-library/reagent-concentrations.html

8. ATTACHMENTS

Attachment 1 Solution Label

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