Standard Operating Procedure (SOP)

Reagent Preparation and Quality Control

This SOP details the standardized procedures for **reagent preparation and quality control**, including the accurate measurement and mixing of chemical reagents, ensuring reagent purity and stability, calibration of equipment used, documentation of batch records, routine quality assessments, and corrective actions for non-conforming reagents. The goal is to maintain reagent consistency and reliability to support accurate experimental results and laboratory safety.

SOP Number	[Enter Number]	**Revision Number**	[Enter Revision]
Effective Date	[Enter Date]	**Approval**	[Enter Name/Signature]

1. Purpose

To provide standardized methods for the preparation and quality control of reagents to ensure consistency, reliability, and safety in laboratory operations.

2. Scope

This procedure applies to all laboratory personnel involved in reagent preparation, handling, and quality control within the laboratory.

3. Responsibilities

- Laboratory personnel: Follow this SOP during all reagent-related activities.
- Laboratory supervisor/manager: Ensure compliance, review records, and address discrepancies.
- Quality control personnel: Conduct assessments and manage documentation.

4. Materials and Equipment

- Chemicals and reagents (analytical grade unless otherwise specified)
- Calibrated balances and pipettes
- Appropriate glassware and mixing devices
- Labels and batch record forms
- PPE (lab coat, gloves, goggles, etc.)
- Calibration standards and QC materials

5. Procedure

1. **Reagent Preparation**
   - Verify chemical identity, grade, and expiration date.
   - Calculate required quantities for the final volume/concentration desired.
   - Use clean, calibrated equipment for measurement and preparation.
   - Mix thoroughly until fully dissolved; label container clearly with name, concentration, preparation date, preparer's initials, and expiry date.
2. **Equipment Calibration**
   - Calibrate balances and pipettes prior to reagent preparation using certified standards. Document calibration results.
3. **Quality Control**
   - Visually inspect reagents for clarity, color, and particulate matter.
   - Perform tests as required (e.g., pH, concentration validation) and document results.
   - Store reagents under recommended conditions to maintain stability.
4. **Documentation**
   - Complete batch records for each reagent preparation, including lot numbers, expiration dates, preparer's and reviewer's signatures.
   - File QC assessment records and calibration certificates.
5. **Corrective Actions**
   - Segregate and label any non-conforming reagent as â€œQuarantine-Do Not Use.â€
   - Investigate root cause, document findings, and implement corrective actions.
   - Re-prepare or dispose of failed reagent as per hazardous waste protocols.

6. References

- Laboratory Quality Manual
- Manufacturer's Instructions and Safety Data Sheets (SDS)
- Relevant regulatory guidelines

7. Appendices

- Sample Batch Record Form
- Calibration Log Sheet