SOP: Sampling and Quality Testing Procedures

This SOP details **sampling and quality testing procedures** to ensure consistent product quality and compliance with industry standards. It includes guidelines for sample collection, handling, and storage, along with standardized testing methods and quality assessment criteria. The procedure aims to provide accurate and reliable data to support quality control and assurance throughout the production process.

1. Purpose

To establish standardized procedures for the collection, handling, and quality testing of samples to ensure product consistency and compliance with regulatory and customer requirements.

2. Scope

This SOP applies to all personnel involved in sample collection, handling, storage, and quality testing across production facilities.

3. Responsibility

- **Quality Control (QC) Personnel:** Perform sample collection, testing, and documentation.
- **Production Staff:** Support in proper sample identification and transfer.
- **Quality Assurance (QA) Manager:** Review and approve testing results; ensure SOP compliance.

4. Definitions

- **Sample:** A representative portion of material/product selected for testing.
- **Quality Testing:** Analytical processes to assess compliance with defined product specifications.

5. Materials and Equipment

- Sampling containers (sterile where applicable)
- Labels and markers
- Personal protective equipment (PPE)
- Standardized test kits/instruments
- Logbooks or electronic data systems

6. Procedure

1. **Sample Collection**
    - Identify sampling points as per production batch or lot.
    - Use clean, appropriate containers for each sample.
    - Label samples with batch number, date, time, and collector's initials.
    - Collect samples aseptically to prevent contamination.
2. **Sample Handling and Storage**
    - Store samples at specified conditions to retain integrity (e.g. temperature, light protection).
    - Minimize sample handling to avoid contamination or deterioration.
    - Document storage location and conditions in the logbook.
3. **Quality Testing**
    - Select and prepare testing method as per standard operating procedures.
    - Calibrate testing equipment before use.
    - Analyze samples according to approved methods (e.g., chemical, physical, microbiological tests).
    - Record all results accurately, noting any anomalies or deviations.
4. **Quality Assessment**
    - Compare results with accepted product specifications.
    - Document pass/fail status and initiate corrective actions for failed samples.
5. **Documentation**
    - Record all sampling and testing activities in the designated logbook or electronic system.
    - Maintain traceability for each sample from collection to result.

7. Quality Control and Assurance

- All equipment must be calibrated and maintained as per manufacturer's instructions.
- QC personnel must receive appropriate training in sampling and testing procedures.
- Deviations from SOP must be documented and investigated.

8. References

- Relevant industry standards (e.g., ISO, GMP, or regulatory guidelines)
- Internal company policies and procedures
- Manufacturer's equipment manuals

9. Revision History

Version	Date	Description	Approved By
1.0	2024-06-25	Initial issue	QA Manager