Standard Operating Procedure (SOP)

Sampling and Testing Methodologies for Finished Goods

This SOP details the **sampling and testing methodologies for finished goods**, outlining procedures for selecting representative samples, preparing samples for analysis, and conducting tests to ensure product quality and compliance with specifications.

1. Purpose

To establish uniform procedures for sampling and testing finished goods to maintain consistent product quality, comply with regulatory requirements, and meet customer expectations.

2. Scope

This SOP applies to all finished goods produced by [Company/Department name] and covers sampling, sample preparation, testing, data recording, and interpretation.

3. Responsibilities

- **Quality Assurance (QA):** Ensure SOP compliance, approve sampling and testing plans.
- **Laboratory Personnel:** Perform sampling, preparation, and testing.
- **Production Staff:** Present finished goods for sampling and testing.
- **Supervisors:** Monitor adherence and escalate non-conformities.

4. Definitions

- **Finished Goods:** Products that have completed the final stage of production and are ready for sale.
- **Representative Sample:** A portion of material that accurately reflects the characteristics of the batch.
- **Test Methods:** Validated analytical or physical procedures used for quality assessment.

5. Sampling Procedure

1. Review production records and batch identification.
2. Determine sample size and frequency as per sampling plan (see **Table 1** below).
3. Label and use clean, calibrated sampling tools.
4. Randomly select samples ensuring the entire batch is adequately represented.
5. Record sample identification details and storage conditions.

Batch Size	Number of Samples	Sampling Frequency
< 100 units	3	Each batch
100â€“1,000 units	5	Each batch
> 1,000 units	8	Each batch

6. Sample Preparation

1. Ensure samples are free of contamination and promptly transferred to laboratory.
2. Prepare samples according to standard method (e.g., homogenization, aliquoting, dilution).
3. Maintain chain-of-custody documentation.
4. Label prepared samples with product, date, batch, and operator initials.

7. Testing Methodologies

1. Use only validated and approved test methods per product specification.
2. Ensure all testing equipment is calibrated and maintained (see Section 8).
3. Conduct required assays (e.g., appearance, chemical composition, potency, microbiological tests).
4. Record results promptly and accurately with reference to sample identification.

8. Equipment Calibration and Test Methods Validation

- Calibrate equipment as per schedule and document calibration status before use.

- Validate new test methods prior to implementation and review at least annually.
- Maintain calibration and validation records.

9. Data Recording and Interpretation

- Ensure complete and accurate documentation of sampling and test results.
- Compare results against product specifications and regulatory requirements.
- Investigate and document any out-of-specification (OOS) results.
- Report trends and non-conformities to QA for action.

10. References

- Product Specifications
- Current Good Manufacturing Practice (cGMP) Guidelines
- Regulatory Authority Requirements (e.g., FDA, EMA)

11. Revision History

Version	Date	Description	Approved By
1.0	2024-06-06	Initial SOP release	[Approver Name]