SOP: Initial Batch Testing and Process Sign-off

This SOP defines the procedures for **initial batch testing and process sign-off**, ensuring that all production batches undergo rigorous quality and safety checks before full-scale manufacturing. It covers sample collection, laboratory analysis, compliance verification, documentation requirements, and final approval criteria, facilitating consistent product quality and regulatory adherence.

1. Purpose

To establish a standardized procedure for initial batch testing and process sign-off to ensure product quality, safety, and regulatory compliance.

2. Scope

This SOP applies to all new product batches manufactured within the facility, covering sample collection, laboratory testing, documentation, and process approval activities.

3. Responsibilities

- **Production Department:** Prepares batches, collects samples, and provides process data.
- **Quality Control (QC) Laboratory:** Conducts analytical and safety testing on batch samples.
- **Quality Assurance (QA):** Verifies documentation, test results, and compliance; authorizes process sign-off.
- **Regulatory Affairs:** Ensures conformity with relevant regulations and standards.

4. Definitions

- **Batch:** A specific quantity of product produced under uniform conditions.
- **Sign-off:** Formal approval indicating a batch has met all acceptance criteria.

5. Procedure

1. **Sample Collection**
   - Collect representative samples from each batch as per sampling plan.
   - Label all samples clearly with batch number, date, and sampler's name.
2. **Laboratory Analysis**
   - Submit samples to QC laboratory with completed sample submission form.
   - Conduct required analytical and safety tests as per product specification.
   - Document all test results in the laboratory notebook and QC database.
3. **Compliance Verification**
   - Compare test results against product specifications and regulatory standards.
   - Investigate and document any deviations or out-of-specification results.
4. **Documentation Requirements**
   - Complete the Batch Record Form, attaching all laboratory results and investigation reports (if any).
   - Maintain an electronic and/or hard copy of all related documentation.
5. **Final Approval & Sign-off**
   - QA reviews all documentation, test results, and ensures compliance has been met.
   - If acceptance criteria are met, QA completes the process sign-off form and authorizes batch release.
   - If criteria are not met, QA initiates corrective actions or batch rejection as per deviation management SOP.

6. Documentation

Document	Description	Retention Period

Batch Record Form	Details batch production steps and sample records	As per company policy
Laboratory Test Reports	Results of all QC/QA tests performed	As per company policy
Sign-off/Approval Form	Formal record of approval or rejection	As per company policy

7. Approval Criteria

- All test results meet defined specifications and regulatory requirements.
- No unresolved deviations or out-of-specification findings.
- All batch and testing documentation is complete, accurate, and signed.
- QA has authorized the process with formal sign-off.

8. References

- Current Good Manufacturing Practice (cGMP) guidelines
- Company Quality Manual
- Product-specific specifications

9. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-10	Initial SOP release	QA Manager