SOP: Finished Product Inspection, Reconciliation, and Rejection Handling

This SOP defines the process for **finished product inspection, reconciliation, and rejection handling** to ensure that all products meet quality standards before distribution. It includes criteria for product inspection, identification and documentation of non-conformities, procedures for product reconciliation to account for discrepancies, and guidelines for the appropriate handling, segregation, and disposition of rejected items. The goal is to maintain product integrity, minimize defects, and ensure compliance with regulatory and company quality requirements.

1. Purpose

To define the standardized procedures for inspection, reconciliation, and handling of rejected finished products to ensure quality and compliance prior to distribution.

2. Scope

This SOP applies to all finished product batches produced at [Facility/Company Name] prior to their release and distribution.

3. Responsibilities

- **Quality Assurance (QA):** Oversees the execution of inspection and reconciliation, verifies documentation, and coordinates rejection handling.
- **Production:** Notifies QA of batch completion, assists with counting and identification, and segregates rejected products.
- **Warehouse:** Supports storage, movement, and destruction/disposal as per rejection disposition.

4. Definitions

- **Non-conformity:** Any deviation of the finished product from set specifications or standards.
- **Reconciliation:** The process of comparing actual finished product quantity with theoretical yield to identify discrepancies.
- **Rejected Product:** Any product failing to meet quality requirements and deemed unfit for release.

5. Procedure

5.1 Finished Product Inspection

1. QA receives notification of batch completion.
2. Perform visual and/or sampling inspection as per specifications (see Table 1).
3. Document results in the Finished Product Inspection Record (FPIR).
4. Identify and tag non-conforming units. Segregate from acceptable product.

5.2 Reconciliation

5. Compare the total count of finished product (acceptable + rejected) to the theoretical batch yield.
6. Document yield reconciliation in the Batch Reconciliation Report.
7. Investigate discrepancies greater than [set %] and report findings to QA Manager.

5.3 Rejection Handling

8. Clearly label and segregate rejected products in designated area.
9. Document rejection details (batch, quantity, reason, date) in the Rejection Log.
10. Determine disposition route (rework, destruction, return) as per QA decision and SOP guidelines.
11. Authorize and document final disposition; update inventory records accordingly.

6. Documentation

- Finished Product Inspection Record (FPIR)

- Batch Reconciliation Report
- Rejection Log
- Destruction/Disposal Records

7. Inspection Criteria (Table 1)

Parameter	Specification	Inspection Method	Acceptance Criteria
Appearance	No visible defects (cracks, discoloration, contamination)	Visual Inspection	100% units conform
Labeling	Correct, legible, and complete	Label Check	100% units conform
Packaging	Intact, sealed, meets specification	Physical Check	100% units conform
Quantity	Matches batch yield +/- allowable variance	Counting	Within specified tolerance

8. References

- Relevant GMP Guidelines
- Company Quality Manual
- Batch Manufacturing Record (BMR) SOP

9. Revision History

Version	Date	Changes	Approved By
1.0	[YYYY-MM-DD]	Initial release	[Name/Title]