SOP: In-process Quality Checks and Recording Requirements

This SOP defines the **in-process quality checks and recording requirements** to ensure continuous monitoring and verification of product quality during manufacturing. It covers the procedures for conducting systematic inspections at various stages of production, criteria for quality acceptance, methods for documenting findings, and protocols for handling deviations. The objective is to maintain product consistency, identify defects early, and support traceability through accurate and timely record-keeping.

1. Purpose

To outline standardized procedures for in-process quality checks and ensure accurate recording throughout manufacturing operations.

2. Scope

This SOP applies to all production lines and personnel responsible for quality assurance within the facility.

3. Definitions

- **In-process Check:** Quality verification conducted during production, before the final product stage.
- **Deviation:** Any departure from approved processes, specifications, or procedures.
- **Acceptance Criteria:** Predefined quality standards that products or processes must meet.

4. Responsibilities

- **Quality Assurance (QA) Personnel:** Conduct in-process checks, document results, and escalate deviations.
- **Production Staff:** Cooperate with QA during inspections and implement corrective actions as needed.
- **Supervisors/Managers:** Review records, ensure compliance, and address process improvements.

5. Procedure

1. **Inspection Points:**
   - Identify and define critical points in the production process for quality checks (e.g., ingredient addition, assembly, packaging).
2. **Conducting Checks:**
   - Follow approved checklists or inspection forms.
   - Use calibrated measuring instruments/tools as required.
   - Assess product against acceptance criteria (see table below).
3. **Documentation:**
   - Record findings promptly in designated logbooks or electronic systems.
   - Entries must include date/time, inspector name, results, and signatures/initials.
4. **Deviation Handling:**
   - Immediately document and report any non-conformances.
   - Follow escalation and corrective action protocols per company policy.

Acceptance Criteria Example

Inspection Point	Parameter	Acceptance Criteria	Frequency
Ingredient Addition	Quantity Added	Â±2% of specified amount	Each batch
Assembly	Component Alignment	No visible misalignment	Every 2 hours
Packaging	Seal Integrity	No leaks or defects	Every shift

6. Recording Requirements

- Complete all fields in logbooks or forms; avoid blank or inaccurate entries.
- Records should be ink-written or electronically secured; corrections require date, reason, and initials.
- Retain records according to company record retention policies.

7. Review and Approval

This SOP shall be reviewed annually, or upon significant process changes, to ensure ongoing suitability and compliance.

8. References

- Quality Management System Manual
- GMP Guidelines
- Company Record Retention Policy