SOP: In-Process Quality Control and Inspection Checkpoints

This SOP details the **in-process quality control and inspection checkpoints** essential for maintaining product standards throughout the manufacturing cycle. It includes procedures for monitoring critical control points, conducting regular inspections, documenting findings, addressing deviations promptly, and ensuring compliance with quality specifications. The goal is to detect and correct defects early, optimize production efficiency, and deliver consistent, high-quality products.

1. Purpose

To outline systematic procedures for in-process quality control and inspection, ensuring consistent product quality and compliance with standards at each stage of manufacturing.

2. Scope

This SOP applies to all personnel involved in production, quality control, and quality assurance within the manufacturing facility.

3. Definitions

- **Critical Control Point (CCP):** A stage in the production process where control can be applied to prevent or eliminate product defects.
- **Deviation:** Any departure from approved procedures or specifications.
- **Inspection Checkpoint:** Specific stage(s) within manufacturing designated for quality assessment.

4. Responsibilities

- **Production Staff:** Execute assigned quality control checks and report anomalies.
- **Quality Control (QC) Personnel:** Monitor CCPs, conduct inspections, document findings, and initiate corrective actions as necessary.
- **Production Supervisor:** Ensure procedures are followed and deviations are addressed promptly.
- **Quality Assurance (QA):** Oversee compliance and approve corrective actions.

5. Procedure

1. **Identify Critical Control Points**
    - Review the manufacturing process and define all CCPs requiring inspection.
2. **Inspection Schedule and Checkpoints**

Checkpoint	Responsible	Inspection Criteria	Frequency
Raw Material Receipt	QC	Visual inspection, supplier COA, label check	Each batch
Mixing/Blending	Production/QC	Homogeneity, weight/volume checks	Every batch
Filling/Assembly	Production/QC	Correct volume/weight, component presence	Hourly
Packaging	QC	Label accuracy, seal integrity	Random, per shift

3. **Conduct Inspections**
    - Perform inspections according to the specified schedule and document all findings using standardized forms or digital systems.
4. **Documentation**
    - Record inspection outcomes, deviations, root causes, and corrective actions in QC logs.
5. **Deviation Handling**
    - If deviation is identified, halt the process if necessary, investigate, and implement corrective/preventive actions (CAPA).
    - Escalate critical deviations to QA immediately.
6. **Review and Release**
    - QA reviews inspection records before final product release.

6. Records

- In-process inspection forms
- QC logs
- Deviation and CAPA reports

7. References

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

8. Revision History

Revision	Date	Description	Approved By
01	2024-06-20	Initial SOP Issue	QA Manager