SOP: In-Process Quality Control Checks and Documentation

This SOP describes the procedures for **in-process quality control checks and documentation**, including systematic monitoring of production stages, verification of product specifications, identification of non-conformities, and accurate recording of all inspection results. The objective is to ensure consistent product quality, early detection of defects, and comprehensive documentation for traceability and continuous improvement within the manufacturing process.

1. Purpose

To define the standardized process for conducting in-process quality control (IPQC) checks and maintaining thorough documentation to ensure consistent product quality and compliance with specifications.

2. Scope

This SOP applies to all operators, QC personnel, and supervisors involved in the **manufacturing and production processes** requiring in-process quality checks.

3. Definitions

- **In-Process Quality Control (IPQC):** Inspection and testing activities performed during different stages of production.
- **Non-conformity:** Deviation from specified requirements or standards.
- **Batch Record:** A documented record of production, control, and quality checks for each lot or batch.

4. Responsibilities

- **Production Staff:** Conduct checks as specified.
- **QC Personnel:** Verify results, report non-conformities, and document outcomes.
- **Supervisors:** Ensure adherence to SOP and initiate corrective actions as needed.

5. Procedure

1. **Preparation**
    - Review work instructions, product specifications, and previous batch records.
    - Calibrate and prepare measuring equipment as required.
2. **Sampling and Inspection**
    - At defined checkpoints, collect samples according to the **sampling plan**.
    - Perform checks for critical parameters (e.g., weight, dimensions, appearance).
3. **Verification of Specifications**
    - Compare results to product specifications and tolerance limits.
4. **Identification and Handling of Non-conformities**
    - Immediately segregate non-conforming items; affix "Hold/Reject" tags.
    - Document details and inform the supervisor for further action.
5. **Documentation**

- Record all results in the **IPQC checklist** or batch record (see template below).
- Include date, time, parameter checked, specification, result, inspector's name, and remarks.

6. **Reporting and Traceability**
   - Ensure all records are signed, dated, and archived according to document control procedures.

6. Documentation Templates

Date/Time	Process Step	Parameter	Specification	Result	Conformity (Y/N)	Inspector	Remarks	Signature
2024-06-20 10:00	Mixing	Viscosity	50-60 cP	58 cP	Y	J. Doe	-	

7. Records and Archiving

- Maintain records for a minimum of **5 years** or as required by regulatory guidelines.
- All documents must be controlled and readily retrievable for audits and reviews.

8. References

- Current Good Manufacturing Practices (cGMP) Guidelines
- Internal Quality Manual
- Relevant Product Specifications

9. Revision History

Version	Date	Description of Change	Author	Approved By
1.0	2024-06-20	Initial issue	QMS Team	QA Manager