SOP: In-Process Quality Assurance Checks and Sampling

This SOP details **in-process quality assurance checks and sampling** to ensure consistent product quality during manufacturing. It covers procedures for regular inspection, testing, and sampling at defined stages of the production process, criteria for acceptance and rejection, documentation requirements, and corrective actions to address deviations. The purpose is to maintain high-quality standards, detect and resolve issues promptly, and comply with regulatory and customer specifications throughout the production cycle.

1. Purpose

To establish a standardized procedure for conducting in-process quality assurance checks and sampling during manufacturing, ensuring consistent adherence to quality standards and regulatory requirements.

2. Scope

This SOP applies to all stages of the production process where in-process inspection, testing, and sampling are required.

3. Responsibilities

- **Quality Assurance (QA) Team:** Conducts inspections, sampling, and testing; documents findings and recommends corrective actions.
- **Production Staff:** Coordinates with QA; ensures process parameters are adhered to and deviations reported immediately.
- **Supervisors/Managers:** Review documented results and ensure implementation of corrective measures.

4. Procedure

4.1 Sample Points and Frequency

- Identify critical control points/stages where sampling and checks will occur.
- Define sampling frequency based on regulatory or internal guidelines (e.g., every batch, hourly, per shift).

4.2 Sampling Method

- Use validated sampling tools and techniques.
- Collect representative samples from designated locations at each sample point.
- Label all samples with date, time, batch number, and sampler's initials.

4.3 In-Process Checks

- Perform visual inspections, measurements, and analytical tests as required (e.g., weight, dimensions, pH, moisture).
- Record results in the in-process quality log.

4.4 Acceptance and Rejection Criteria

Parameter	Acceptance Criteria	Rejection Criteria
Appearance	No discoloration, contamination, or visible defects	Any visible defects or contamination
Dimensions/Weight	Within specified tolerance	Outside specified range
Critical Analytical Test	Results within specified limits	Results outside specified limits

4.5 Documentation

- Record all inspection, sampling, and test results in the designated log or electronic quality management system (eQMS).
- Document non-conformances and notify relevant personnel immediately.

4.6 Corrective Actions

- Investigate root cause of any deviations.
- Implement corrective and preventive actions (CAPA) as required.
- Document actions taken and outcome.

5. References

- Company Quality Manual
- Regulatory Guidelines (e.g., ISO, GMP)
- Customer Specifications

6. Revision History

Version	Date	Description	Approved By
1.0	2024-06-15	Initial version released	QA Manager