Standard Operating Procedure
In-Process Monitoring and Quality Sampling Protocols

This SOP details **in-process monitoring and quality sampling protocols**, including procedures for continuous observation of production parameters, sampling techniques during various manufacturing stages, criteria for sample selection, documentation of monitoring results, handling of non-conformities, and coordination with quality control laboratories. The goal is to maintain product quality and consistency by ensuring timely detection of deviations and implementing corrective actions throughout the production process.

1. Purpose

To define and standardize the procedures for in-process monitoring and quality sampling during manufacturing, ensuring ongoing product quality, detection of deviations, and timely corrective action.

2. Scope

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

3. Responsibilities

- **Production Personnel:** Conduct in-process checks, collect samples, and record results.
- **Quality Control (QC) Personnel:** Analyze samples, review documentation, and report deviations.
- **Supervisors/Managers:** Ensure SOP compliance, review records, and initiate corrective actions as needed.

4. Procedure

4.1 In-Process Monitoring

- Monitor critical production parameters (e.g., temperature, pressure, mixing time) at predefined intervals as per batch record or process instructions.
- Use calibrated instruments and maintain logbooks for all observations.
- If parameters are out of acceptable range, halt the process and report to supervisor immediately.

4.2 Sampling Techniques

- Collect samples during key process stages (start, intermediate, end, or as specified in the batch record).
- Use clean, labelled containers and follow aseptic technique to avoid contamination.
- Sampling locations and frequency should be as per approved sampling plan for each product/process.

4.3 Criteria for Sample Selection

- Samples must represent the entire batch or process stage.
- Select samples randomly unless otherwise specified (e.g., targeted sampling for process validation or investigation).
- The sample quantity should suffice for all required tests plus retain sample requirements.

4.4 Documentation

- Record all monitoring results and sample details (date/time, process stage, parameter values, sampler's name) in the designated logbook or batch record.
- Attach identification labels to all samples and submit sampling forms to the QC laboratory.

4.5 Handling Non-Conformities

- Report any deviations or non-conforming results to supervisor and QA immediately.
- Document details of the non-conformity, including batch number, affected process parameter, and corrective action taken.
- Quarantine affected material until investigation and disposition decision are finalized.

4.6 Coordination with QC Laboratory

- Deliver samples promptly to the QC laboratory along with complete documentation.
- Retain a duplicate record of sample submission and test results in the production or QA records.
- Implement QC feedback or corrective action recommendations as required.

5. Documentation/Records

- In-process monitoring logs
- Sampling records and sample labels
- QC analysis reports
- Deviation/non-conformity reports
- Corrective and preventive action (CAPA) records

6. References

- Relevant batch manufacturing records
- Approved sampling plans
- GMP guidelines
- Quality manuals and policies

7. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-01	Initial template release	QA Manager