Standard Operating Procedure (SOP)
Batch Production and Process Flow Control

1. Purpose

This SOP defines the **batch production and process flow control** procedures, including the planning, monitoring, and management of production batches, control of process parameters, documentation of production data, quality assurance checkpoints, and corrective actions for deviations. Its objective is to ensure consistent product quality, optimize production efficiency, and maintain compliance with regulatory standards throughout the manufacturing process.

2. Scope

This SOP applies to all manufacturing personnel involved in batch production, process control, and related quality assurance activities.

3. Responsibilities

- **Production Manager:** Overall implementation and supervision of batch production and process flow.
- **Operators:** Execution of production processes and accurate documentation.
- **Quality Assurance (QA):** Monitoring compliance, performing inspections, and managing deviations.
- **Maintenance:** Ensures equipment used is properly maintained and calibrated.

4. Definitions

- **Batch:** A defined quantity of product processed in one run following the same production order.
- **Process Parameters:** Critical variables like temperature, pressure, time, etc., that must be controlled.
- **Deviation:** Departure from an approved process or parameter.

5. Procedure

1. **Batch Planning and Authorization**
    - Verify production plan and order specifications.
    - Document batch number, date, and responsible persons.
    - Approve materials and equipment before use.
2. **Process Flow Control**
    - Follow defined process flow diagrams and production instructions.
    - Monitor and record critical process parameters at all identified control points.
3. **In-process Monitoring**
    - Perform real-time checks (e.g., sampling, weight, temperature) as specified in process instructions.
    - Document results and verify against preliminary specifications.
4. **Batch Documentation**
    - Complete batch production records (BPR), including ingredient lot numbers, process times, and operator signatures.
    - Attach supporting documents such as process parameter logs and equipment calibration certificates.
5. **Quality Assurance Checkpoints**
    - Conduct predefined in-process inspections and final quality checks.
    - Document QA findings and release or reject batch based on results.
6. **Deviation and Corrective Actions**
    - Identify, document, and report any deviations from the approved process.
    - Implement corrective and preventive actions (CAPA) as required, and document outcomes.

6. Documentation and Records

- Batch production record (BPR) and process parameter logs must be completed and reviewed for each batch.
- Deviation reports and CAPA records should be maintained.

7. References

- Manufacturing Master Batch Record (MBR)
- Quality Assurance Procedures
- Applicable Regulatory Guidelines (e.g., cGMP, ISO standards)

8. Revision History

Revision	Date	Description	Approved By
00	YYYY-MM-DD	Initial issue	[Name/Signature]