SOP: Product Identification and Lot/Batch Numbering System

1. Purpose

This SOP details the **product identification and lot/batch numbering system**, covering the methods for uniquely identifying products, assigning lot and batch numbers, and maintaining traceability throughout the production and distribution processes. The procedure ensures accurate tracking for quality control, recall management, and regulatory compliance.

2. Scope

This SOP applies to all finished products manufactured, packaged, stored, or distributed by [Company Name], including intermediates and bulk products as required.

3. Responsibilities

- **Production Manager:** Ensures correct assignment of product codes and lot/batch numbers.
- **Quality Assurance (QA):** Monitors compliance with this procedure, verifies documentation.
- **Warehouse/Logistics:** Maintains records for traceability throughout storage and distribution.
- **All Staff:** Adheres to this SOP during relevant operations.

4. Definitions

Term	Definition
Product Identification Code (PIC)	Unique alphanumeric code that distinguishes each product type.
Lot Number	Identification assigned to a group of units originating from a specific manufacturing run.
Batch Number	Similar to lot number; usually refers to a quantity of material processed together.
Traceability	Ability to track the history, application, or location of a product using recorded information.

5. Procedure

1. **Product Identification**
   a. Each product must be assigned a unique Product Identification Code (PIC) generated by the QA department according to the Product Code Format (see section 6).
   b. The PIC must be included on all product labels, packaging, and documentation.
2. **Lot/Batch Number Assignment**
   a. For every production run, assign a unique lot or batch number using the Lot/Batch Numbering Format (see section 6).
   b. Record the lot/batch number in the batch manufacturing record and on all associated labels.
3. **Labeling**
   a. Ensure that all products are properly labeled with both the PIC and lot/batch number before release from production.
   b. Any product with incomplete or incorrect labeling must be quarantined and investigated.
4. **Documentation and Records**
   a. Maintain a Product Identification Register and a Lot/Batch Record for all products.
   b. Records must be retained for a minimum of [X years] as per regulatory requirements.
5. **Traceability and Recall**
   a. Ensure the assigned codes allow product traceability from raw materials through to distribution.
   b. In the event of a recall, use the codes to identify all affected products quickly.
6. **Change Control**
   a. Any changes to code formats or assignment procedures must be authorized by the QA department and documented according to the Change Control SOP.

6. Numbering Format

Code Type	Format Example	Description
Product Identification Code	PROD-XYZ-001	Three-part code: product family, product type, sequential number.
Lot/Batch Number	YYMMDD-BATCHSEQ	Date of manufacturing (YYMMDD), followed by sequential batch number for the day (e.g., 230612-01).

Note: Refer to company-specific code conventions if applicable.

7. References

- Current Good Manufacturing Practices (cGMP)
- Company Change Control SOP
- Regulatory guidelines as applicable

8. Revision History

Version	Date	Description	Approved By
1.0	[DATE]	Initial version	[NAME/TITLE]