

Standard Operating Procedure

Title: Procedure Product Identification and Traceability

Procedure

1. Introduction

Product traceability system allows for complete and up to date histories of all batches of products from the starting materials to the complete final product. Identification and status of materials is provided by unique and controlled numbering system. The system can be interrogated to provide reports to allow for full traceability.

2. General Overview

2.1. Inwards goods

- 2.1.1. Materials/Components are identified at the time of receipt. Each material has a unique identifying number. At the time of receipt each material shipment is given an unique Laboratory batch number. QA team maintains the full list of raw material and component codes, description and approved suppliers/manufacturers.
- 2.1.2. The vendor's batch number of the imported raw materials are maintained all through the process steps associated with the unique Laboratory batch numbers.
- 2.1.3. The raw material code number is allocated and maintained by the Quality Assurance Team. Laboratory batch number is given by Warehouse team.
- 2.1.4. Each shipment of raw material is given an unique Goods Receipt Slip number. The combination of unique material code, Laboratory batch number and Good Receipt Slip number allows warehouse team a good traceability during storing and issuing materials to production.

2.2. Finished Goods Production

- 2.2.1. All Finished Goods manufactured require two sets of numbers that identify the product type and the unique batch number. Each manufactured product type is identified by unique product code. Each manufactured batch is identified by unique Batch Production Number.
- 2.2.2. The Finished Goods number is assigned and controlled by the Quality Assurance team.
- 2.2.3. The Finished Goods batch number is allocated by the Planner sequentially on conversion of a Planned Order and a batch production Order. The unique Batch Production Number is used to trace all processing steps for the Production Operation.
- 2.2.4. Product identification is noted on the Certificate of Analysis at testing.
- 2.2.5. Product traceability is progressively recorded in the Manufacturing Instruction (MI) system.
- 2.2.6. The product code, Batch Production Number and Goods booking Slip Number in combination produce the system which traces the distribution, recall and destruction of all Finished Goods.

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- 3.10. Goods Booking Slip Number is allocated by production planner to identify each pallet of a Batch booked out of the production line. Each **GBS** number is an eight digit number in the format of **YYXXZZZZ**, starting with the last two digits of the year, followed by a two digits of the month. A consecutive four digits number is assigned up to 1000 booking of batches started from 0001.

For example: GBS number for 10th delivery of the month of June, year 2005 will be **05060010**.

The storage type and storage bin number for product storage is allocated on the Goods Booking Slips.

- 3.11. Pallet IDs are created to identify every pallet of manufactured finished goods, which will contain information of a unique Product code and Batch Production Number.
- 3.12. All steps throughout the Manufacturing Process are tracked via Manufacturing Instruction (MI) documents, maintained by the Technical Service team unique for each product code.
- 3.13. Full traceability is assured through issuing appropriate documentation and maintaining records that accompany every step in batch manufacturing.

4. Status

- 4.1. All components, Raw Materials and Finished Products undergo inspection and testing at various stages of their processing to verify their adherence or otherwise to standards which is detailed in relevant documentation.
- 4.2. On completion of every inspection and test procedure, resulting in a change to the status of the item a record is generated to attest that the item is allowed to proceed to the next stage in its processing.
- 4.3. The change in status of a product/batch can be marked by various ways like Authorised persons signature and date on the forms and records, applying stickers e.g. RELEASED sticker.
- 4.3.1. Only authorised warehouse person will receive incoming goods and sign and date on the Goods Receipt Slips. Authorised dispensary personnel will sample the Raw material/component laboratory testing. Authorised production personnel will request material/component for a BPN through Material Transfer Orders. Authorised laboratory personnel will test Raw Materials, Components and Finished Goods according to approved Specification and Test Reports. In each of the case the material or batch status will be changed, which is reflected by authorised persons sign and date on the forms and record. Appropriate stickers are applied to mark those changes.
- 4.3.2. Goods undergoing manufacturing are continuously in process tested, the status "done/not done" is noted when the entry is made in the Manufacturing Instructions.

5. Records

The completed Manufacturing Instruction (MI) sheets form the record of batch production.