

1 Purpose

The purpose of this Guideline is to describe the receipt, handling and storage of starting materials and packaging materials. The handling also includes sampling.

2 Scope and Applicability

This Guideline is applicable to all manufacturing units, its joint ventures, licensees and contractors performing manufacturing, packaging and repackaging including labeling and change of leaflets.

3 Definitions

3.1 Starting Materials

Any material used in the production of an API, intermediate or a formulated product, but excluding packaging material

3.2 Packaging Materials

Any material employed in the packaging of a medicinal product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

3.3 Printed Packaging Materials

Printed packaging materials are printed and/or otherwise decorated. In the case of printed packaging components for finished products, the text, and in some cases the decoration, forms a part of the legal labeling and design of the finished products, (e.g. labels, leaflets, pre-printed ampoules, tubes, foils).

4 Responsibilities

4.1 It is the responsibility of each site to have a written procedure, which describes the process for the receipt, handling and storage of starting materials and packaging materials.

4.2 It is the responsibility of the unit conducting the audits of the joint ventures, licensees and contractors to ensure that this International Guideline is adhered to.

5 Guideline

5.1 General Aspects

5.1.1 Receiving and dispatch bays should protect materials and products from the weather. Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.

5.1.2 Suitable conditions for storing and sampling of starting materials and packaging materials shall be provided. Any special storage requirements as demanded by specifications should

5.5.5 Containers from which samples have been taken should be marked to indicate that a sample has been taken. For example; with the persons signature and the sampling date. This will aid any supplementary investigation.

5.6 Quarantine

5.6.1 Quality Assurance/Quality Control shall hold starting materials and packaging materials under quarantine before release. Unprinted secondary packaging materials may be exempted.

5.6.2 Quarantine shall be achieved by either physical quarantine system or by a fully computerized storage system.

5.6.3 If a physical quarantine system is used the materials should be stored in areas designed for this purpose.

5.6.4 If a fully computerized system is applied there is no need for a segregated quarantine area. The system should be designed so that materials are not available for requisition before release. To achieve the necessary guarantee that only released materials are used for processing, the fully computerized system should be properly validated.

5.7 Evaluation and Release

All deliveries of starting materials and packaging materials should be tested, evaluated and released by Quality Assurance/Quality Control as appropriate.

5.8 Return of Materials

A material must be returned to stores only if name, code number and control number identify it and if the integrity of the material during handling is ensured. For starting materials and printed packaging materials the returned quantity should be recorded.

Excess of printed packaging materials bearing batch numbers or other batch specific printing must be destroyed in connection with the line clearance procedure.

5.9 Rejected Materials

Rejected materials shall be clearly labeled as such and should be moved to the area allocated for rejects as soon as possible and should be disposed of without delay.

5.10 Inventory Record

There should be an inventory record for each batch of starting materials and printed packaging materials.

The inventory record should contain sufficient information to allow reconciliation of the use of each batch of materials. All batches of finished products in which a certain material batch has been used should be identified.

The system shall support first in-first out use of components, containers and closures.