1 Purpose

The purpose of this guideline is to describe the way that packaging operations should be conducted.

2 Scope and Applicability

This guideline is applicable to any manufacturing sites, its joint ventures, licensees and contract manufacturers performing packaging and re-packaging, including re-labeling and changing of leaflets.

3 Definitions

3.1 Finished Product

A product which is packaged and labeled for supply to a wholesaler, hospital, pharmacy, doctor or patient.

3.2 Packaging Material

Any material employed in the packaging of an API, intermediate or formulated product, excluding any packaging material 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 Primary Packaging Material

The packaging which is in direct contact with the Formulated Product, Intermediates, Excipients & APIs (includes Devices for delivering dosages).

3.4 Secondary Packaging Material

The packaging which is not in direct contact with the Formulated Product, Intermediates, Excipients & APIs - usually contains the Primary Pack.

3.5 Bulk Formulated Product

A pharmaceutical product (Formulated Drug/Formulated Product) held in large intermediate or shipping containers and ready to be filled into primary containers.

3.6 Repackaging Operations

The activities required to replace, or add to, the primary and secondary packaging included in a finished product to meet a specific market need, or to replace faulty/obsolete primary or secondary packaging, e.g. tablet blisters, patient leaflets and cartons.

3.7 Over-labeling

5.1.1 The packaging operations should comply with official GMP requirements and any other additional company requirement covered in this Guideline or in other documents authorized by the company.

5.1.2 Packaging operations should be conducted in suitable buildings, facilities and conditions. The facilities should provide appropriate environmental protection, segregation and containment for the products being packaged, so as to eliminate the risk of cross contamination, mix ups and/or substitutions.

5.1.3 There should be a Master Batch Packaging Record for each product to be packaged, and packaging batch specific copies made from these.

5.1.4 All commercial finished products should bear a batch number and an expiry date on both primary container labels and cartons.

5.2 Handling of Printed Packaging Materials

5.2.1 Printed packaging materials should be stored and transported in closed containers identified by name, code number and control number.

5.2.2 Printed packaging materials should be stored in secure areas. Additional security measures may be necessary when storing or transporting packaging components used for high value products, particularly components containing anti-counterfeiting devices e.g. holograms.

5.2.3 To minimize the risk of mix-ups, bar-coded roll labels should be used whenever possible, and the bar codes should be read on line just prior to adherence to the primary container.

5.2.4 Over printing of labels and cartons with batch number and expiry date should preferably be performed on line.

5.2.5 If not overprinted on line, packaging materials should be overprinted in a partitioned area. The operation should be documented. Line clearance procedures should be applied also to the overprinting operation.

5.2.6 Specimens of all printed components used should be added to the Batch Packaging Record.

Note: When overprinting is made on line, this includes a specimen of the overprinted labels.

5.2.7 Excess overprinted packaging materials should be destroyed as soon as possible. Excess packaging materials not overprinted may be returned to store, only if identified by code number and control number and if the integrity of the material during handling is ensured. The return should be recorded.

5.2.8 All printed packaging materials must be accounted for at receipt and during usage.

General appearance and completeness of the packages

Integrity of seals and closures

Fill quantity

Correctness and clarity of overprinting and embossing

Correct functioning of line monitors

Continuity of bulk formulated product and packaging material identity and quality

General checks on tidiness/cleanliness of the packaging line and surrounding area

5.5.3 Packed or partially packed product that has been removed for examination, or involved in a deviation, should be reintroduced to the packing operation only after special inspection, investigation and approval by authorized personnel. Note: this should be allowed only if the product has not been removed from the immediate vicinity of the packaging operation.

5.6 Labeling of Primary Packed Product

Filling and sealing should be followed as quickly as possible by labeling of the primary container, including a batch number and expiry date. If the fill/seal and primary labeling operations are discontinuous, the primary containers should be marked with a unique identification code (whenever possible), and secured in containers which are each marked with the name, dose/strength, quantity of primary containers and batch (lot) number.

5.7 Reference Sample

Reference samples of finished products should be drawn according to an established sampling plan.

5.8 Yield Calculation and Reconciliation of Materials

5.8.1 After completion of the filling, packaging and labeling operations a comparison should be made between the quantity of printed packaging material items issued and the quantity of such items used as:

Accepted, labeled and packaged units
Samples
Rejected labeled units and the number of items not otherwise used.

