

Control of Packaging Operation

5.8.3 The results should be entered in the Batch Packaging Record. Discrepancies from pre-set deviation limits should be carefully investigated and recorded. The material should not be released until an acceptable explanation of the discrepancy has been reached.

5.8.4 Excess overprinted packaging materials should be handled as described in Section 5.2.7.

5.9 Handling of Finished Product

5.9.1 Packaged finished product should be quarantined until released by Quality Assurance/Quality Control. This does not preclude shipment between quarantined sections of non-contiguous warehouses, providing that the product stays within the control of the company.

5.9.2 The release procedure should be formalized and include:

A check on the status of the bulk formulated product if packaging was initiated ahead of release.

An evaluation of the Batch Packaging Record.

A check that all printed components are the approved versions for distribution in the markets concerned

A check that finished product has not been released from the site to the markets concerned with later approved versions of printed components. If this is the case finished product with superseded printed components must be repackaged (see Section 5.10).

5.10 Repackaging

5.10.1 The number of repackaging operations should be kept to a minimum.

5.10.2 Repackaging should be carried out in accordance with the requirements for normal packaging operations and repackaged product should pass through a formal release procedure.

5.10.3 Over-labeling of finished products should not be performed. Addition of e.g. price information or similar is allowed. Original labels should not be removed.