

Receipt Handling and Storage of Starting & Packaging Materials

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