



Standard Operating Procedure

Title: Rejection of Materials

Department	Quality Management	Document no	QMS-200		
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Purpose

The purpose of this standard operating procedure is to describe the process to be followed for the rejection of materials at a GMP sites.

Scope

This procedure is applicable to all inventory items. This includes, but is not limited to, finished and intermediate product, master and working seeds, raw materials, packaging, consumables, in-process production and returned goods.

This procedure does not apply to items rejected as a result of reaching expiry or obsolescence.

Responsibilities

Quality Assurance is responsible for:

- Ensuring that this procedure is followed for all material rejections.
- Training of appropriate staff approved to apply status labels.

Logistics Department (Warehouse and Purchasing) is responsible for:

- Raising a SRN when required.
- Moving rejected stock to a reject location.
- Arranging for disposal of rejected goods, or
- Arranging for the return of rejected purchased goods to the supplier.
- Ensuring application of 'Reject' status labels is only performed by personnel trained by QA.

Production is responsible for:

- The disposal of rejected in-process (bulk) products.

Definitions

QRN	QA Rejection Number
QARN	QA Rejection Notification
SRN	Stock Rejection Notification
ERP	Enterprise Resource Planning

General

1. The process of identifying, evaluating and relocating material to be rejected must be performed without delay. This is particularly important for material that is to be returned to the supplier as a delay may compromise company's ability to make a claim on the supplier or insurance agent.
 - 1.1 Photographs should be taken of damaged goods if possible.