YR = Present year

Scope:

This procedure defines the standards and activities for packaging and storage of final product at the Pharma A/S production plant in Lyngby, Denmark.

Summary

Each batch of final API product must have a unique batch number and a unique batch record. These information are stored in the Pharma A/S LIMS (Laboratory Information Management System) system.

An automatic sampling system retrieve a sample of each batch which is sent to the QC laboratory for analytical evaluation.

Raw materials are received and stored in the Logistics warehouse area.

Final products after packaging in the production area, are transported immediately to the cold storage area in the warehouse.

Final product batches are in quarantine until final QA assessment. Approved batches can be released for sale and will appear in the Sales IT system. Non approved batches must be quarantined and await further QA assessment.

Packaging and Labels

Packaging materials and label materials are received by the logistics operators. The materials are checked for integrity and after approval are stored in the appropriate storage facility for packaging and label materials in the warehouse area. Defect materials are separated and discarded.
Packaging and label materials must be kept under hygienic conditions including controlled temperature and humidity.

Packaging and label materials are only retrieved by the logistics operator when they are to be used during the same shift.
The materials must be inspected for any defects before use.

Labels are printed during the start of the shift for the batches and sub-batches to be packaged according to the daily packaging plan.

Unused packaging materials must be returned to storage by end of the shift.
Unused labels must be discarded.

Packaged product must be transported continuously to the appropriate storage area in the warehouse. No product must be left in the packaging area after end of shift.

Only electric driven forklifts are allowed in the packaging and the final product warehouse area.

Sampling for QC control

The automatic sample system will generate into its appropriate sample container, a representative sample from each batch and sub-batch. The samples are automatically transported to and stored in the cooling cabinet next to the packaging unit.

At the end of each shift the logistics operator collect the samples from the shift in the special insulated transportation container and deliver them to the refrigerator for incoming samples in the QC laboratory.

Storage and Warehouse

Raw Materials

Raw materials are received by the Logistics operators. Certificate of Analysis (CoA) are checked by the operator and sent by internal mail to the QA department by the end of the shift. In case of any immediate suspicion about the integrity of the raw material (damaged packaging, odd color, smell or consistence) the QA department is contacted immediately for possible quarantine or rejection of the batch.

Raw materials are used after the FIFO principle.

Final Products

Final products from the packaging area must be stored in warehouse green painted storage areas to await final approval.

Off spec product, rejected or returned product, must be moved immediately to the special yellow painted storage areas and be labelled with special temporarily removable labels showing their actual status.

Temperature and humidity in the storage areas are checked daily twice by the logistics operators; at the start and the end of the shift. The results are noted in the appropriate checklists. The checklists are delivered by the end of the week to the logistics supervisor.

Responsibilities:

This document: Logistics Manager
Daily packaging plan: Logistics assistant
Packaging, labelling, sampling and storage: Logistics operators

Change Log

Version	Description	Initials	Date
1	This is first version	Log Mgr	01.05.(YR-1)
2	Implementation of daily packaging plan	Log Mgr	15.06.(YR-1)
3	Inclusion of raw materials handling	Log Mgr	01.08.(YR-1)