Standard Operating Procedure
Title: Storage or Handling Rules for Inventory Items

Department	Warehouse		Document no	WAR-115	
Title	Storage or Handling Rules for Inventory Items				
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1.0 DOCUMENT OWNER
Warehouse / Quality Manager

2.0 PURPOSE

To outline procedures / guidelines for storage and handling inventory items in the Warehouse at a GMP site. Non-inventory items and consumables of importance are also covered.

3.0 SCOPE

3.1 Inventory Items in ERP

This SOP covers inventory items located at the GMP site. Inventory items consist of:

- Raw Materials (RM);
- Bulk materials (BM) (also called Semi Finished goods or SFG) e.g. tablets / capsules / pastes / vials / blends);
- Packaging Materials (PM); and
- Finished Goods (FG).

3.2 Inventory Items in ERP system

This SOP covers Finished Goods or Semi-Finished Goods at GMP site.

3.3 Non-Inventory Items

This SOP covers Non- Inventory items held in the warehouse. Non- Inventory items are consumables used in production and associated departments that do not feature in the bills of materials. Examples are pallets, plastic bags, plastic containers, disposable gloves, hot melt glue, adhesive tapes, lubricants, and disposable overalls.

4.0 RESPONSIBILITY

4.1 All areas in the warehouse except the receiving area are temperature controlled. Warehouse Manager and QA investigate all temperature / humidity deviations that have GMP or product quality impact (denoted by GMP alarms) and take corrective actions. (SOP QMS-035 Pharmaceutical Deviation Report System.)

4.2 RM / API are always stored in warehouse racks at conditions per directions from QA in warehouse racks.

4.3 Where the required storage temperature is between +2 to +8 degrees C, such items are stored in the Warehouse Fridge.

4.4 Semi-Finished Goods (BM) (purchased and manufactured in plant) and Finished Goods in ERP system are stored in racks in the warehouse in appropriate warehouse zones. Recommended storage

4.19 Production Manager / delegate manages the non-inventory items in the warehouse (ordering, storage, issue and inventory control). Non-inventory items are only stored in their dedicated racks in the warehouse.

4.20 All FG and any SFG for sale are held in ERP system under test in appropriate QA status (e.g. Q status).

4.21 All items meant for distribution out of Warehouse are approved and moved from ERP system.

4.22 All FG and SFG are dispatched from the site if they are in Approved status in ERP system. Lots of any item is selected from those available in ERP system for dispatch based on First Expired First Out rule (FEFO) unless a customer specifically requires a given lot. All other deviations to FEFO rule are approved by QA. FG and SFG may be shipped in Quarantine status if authorized by QA in accordance with SOP **WAR-020** Dispatch of Goods from Warehouse.

4.23 Any inventory item in ERP system that is sold or dispatched to another affiliate or are sent to a third party contractor against a packaging shop order MUST be in approved status in ERP system.

(Exceptions to this rule are samples being sent for analysis / evaluation or testing and goods being returned to suppliers). Appropriate transactions for sale or transfer or dispensing transactions to shop orders have to be carried out in ERP system before such items are dispatched.

4.24 All items that are dispatched from ERP system are allocated to appropriate orders and Warehouse / other logistics operators shall ensure that all instructions for packaging and labelling and dispatch from the consignee are fully complied with and appropriate invoices are raised.

4.25 All customs rules are implicitly followed whilst exporting from GMP site to overseas destinations and export documents are safe kept in the Logistics Department in accordance with the requirements of the local Customs Service.

4.26 All safety requirements of local regulatory bodies are met and EH&S safety guidelines are followed in the Warehouse.

4.27 All trucks carrying incoming inventory items and all trucks for outgoing Inventory items are inspected by warehouse personnel (after they are checked by site security at the gate). Unloading and loading is carried out only after this inspection.

4.28 All inventory items (FG / SFG) leaving GMP site and bound for the local distribution centre are sent in dedicated trucks on non-stop priority basis to ensure that transport temperatures are the same as the site storage temperatures.

4.29 All export airfreight shipments are sent in covered trucks to local depots of the GLSP (Global Logistics Service Provider or Freight Forwarder). Where specified, data loggers are used to monitor transit temperatures.

4.30 Sea Freight shipments are sent in sealed containers through GLSP. Temperature controlled Reefers are used where temperature control of exported items is required. Logistics department review temperature control requirements with QA in all cases and set the temperatures in accordance with the requirements of the transported products. Temperature mapping and data logging of shipped inventory items will be conducted in accordance with the recommendations of QA.

4.31 All items requiring transportation between +2 and +8 degrees Centigrade are specially packed and shipped in containers to maintain these temperatures. Data loggers are used in all such shipments.

4.32 Inventory items requiring special security provisions are handled appropriately per security policy and where required, sealed aircraft cans and sealed shipping containers / reefers are used.

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EH&S	Environmental Health & Safety
FEFO	First Expired First Out
FG	Finished Goods
GLSP	Global Logistics Service Provider
GMP	Good Manufacturing Practice
ERP	Enterprise, Resource & Planning System
PM	Packaging Material
QA	Quality Assurance
RM	Raw Material
SFG	Semi-Finished Goods
WAR	Warehouse