Standard Operating Procedure

Title: Status Labels

Department	Warehouse		Document no	WAR-095
Title	**Status Labels**			
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Purpose

The purpose of this standard operating procedure is to define the meaning of the status labels used at GMP sites.

Scope

This procedure applies to status labels applied to all inventory stored in pharmaceuticals warehouses and used throughout the manufacturing process. This includes but is not limited to raw materials, packaging, consumables, purchased product, contract manufactured product and finished products.

Responsibilities

Quality Assurance:

- Ensure compliance with the requirements of this standard operating procedure.

- Application of Approved, Approved with Restrictions, Released, Rejected, Hold, Approved for Processing, Retention, and Release for Supply labels

- Training of appropriate staff approved to apply Approved, Approved with Restrictions, Rejected, Hold and Release for Supply labels.

  – QA personnel only may apply Released, Approved for Further Processing and Retention labels as these labels are applied using a meto gun and the number of labels issued cannot be controlled.

- Ensure secure storage of all status labels except Inspection and Direct Putaway labels.

Warehouse:

- Ensure all site manufactured semi finished and finished goods inventory which are receipted into stores have a pallet card (refer to Appendix 1) attached to each pallet.

- Ensure all inventory which are receipted into stores have a status label applied (under inspection, direct putaway)

- Ensure application of status labels other than Inspection and Direct Putaway, is only performed by staff trained by QA personnel.
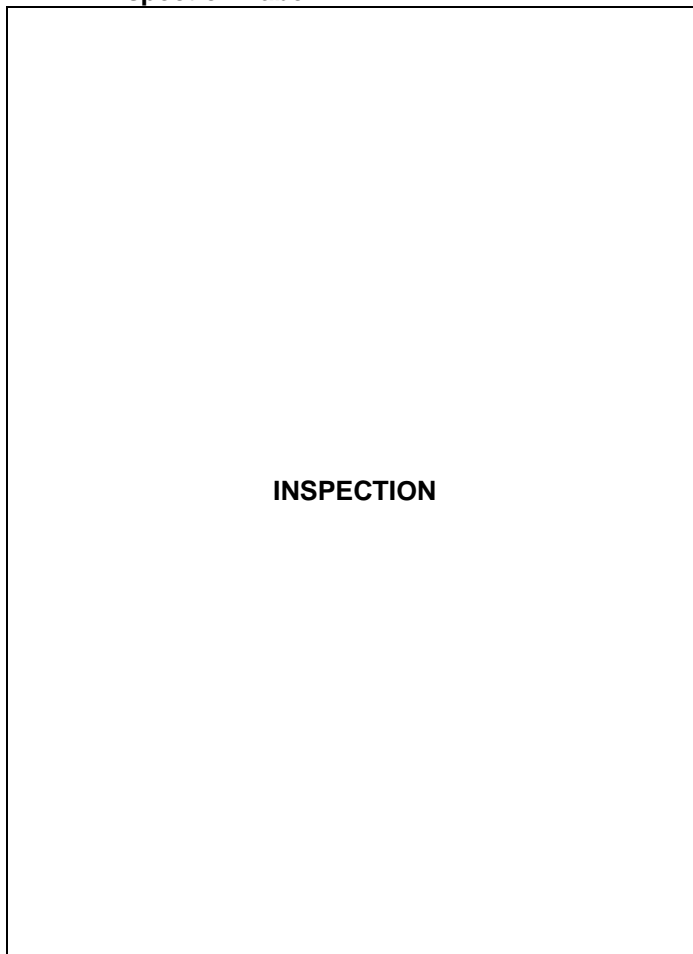
- Ensure secure storage of status labels.

Manufacturing:

Ensure all semi finished or finished goods have a Pallet Card (refer to Appendix 1) attached prior to sending to stores.

1.2 Inspection Label

<table>
<tr><td>

INSPECTION

</td><td>

What this label means:

THIS MATERIAL CAN NOT BE USED IN MANUFACTURING or DISTRIBUTED IN SUPPLY CHAIN

➢ This label is applied by warehouse personnel to incoming goods booked in ERP system in (**Quarantine**) – Purchase Order Receive Goods

➢ These labels are automatically generated by the ERP system.

➢ Manufactured goods booked into Quarantine in the ERP system – Manufacture Order Report Receipt have an 'Under Inspection' pallet card (refer Appendix 1) attached by manufacturing.

➢ These goods require inspection and disposition by QA to be changed to approved for use or released for supply or rejected and not suitable for use in manufacturing or sale.

</td></tr>
</table>

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1.4 Approved with Restrictions Label

APPROVED WITH RESTRICTIONS
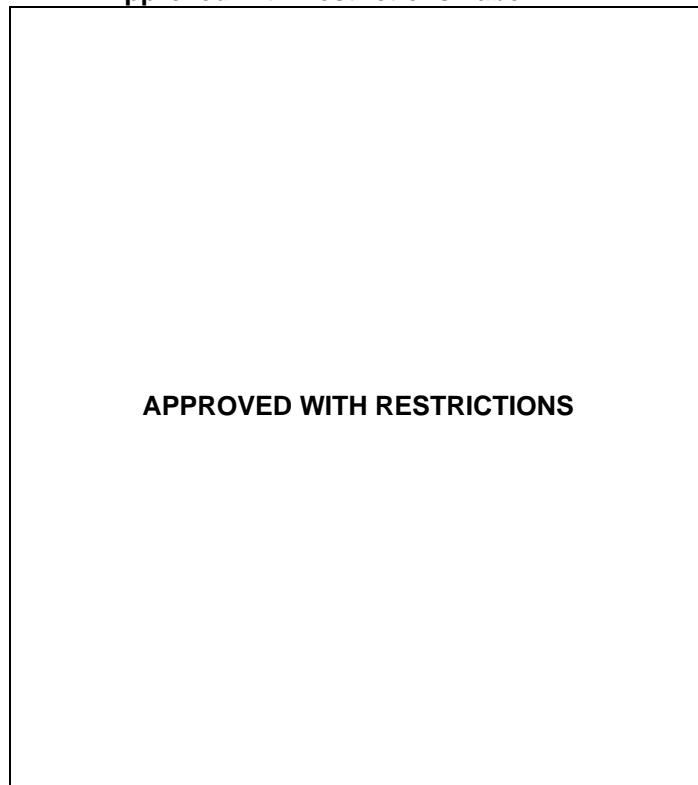
What this label means:

THIS MATERIAL MAY BE USED IN MANUFACTURING but RESTRICTIONS APPLY

➢ This label is applied by QA personnel (or trained warehouse personnel) on completion of a risk assessment identifying restrictions to be applied to the use of the material.

➢ The material is disposition (**approved for use or released for supply**) in the ERP system.

➢ This label lists the restrictions that apply to the use of the material

➢ These labels are generated using the labelview program

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1.7 Release for Supply Label

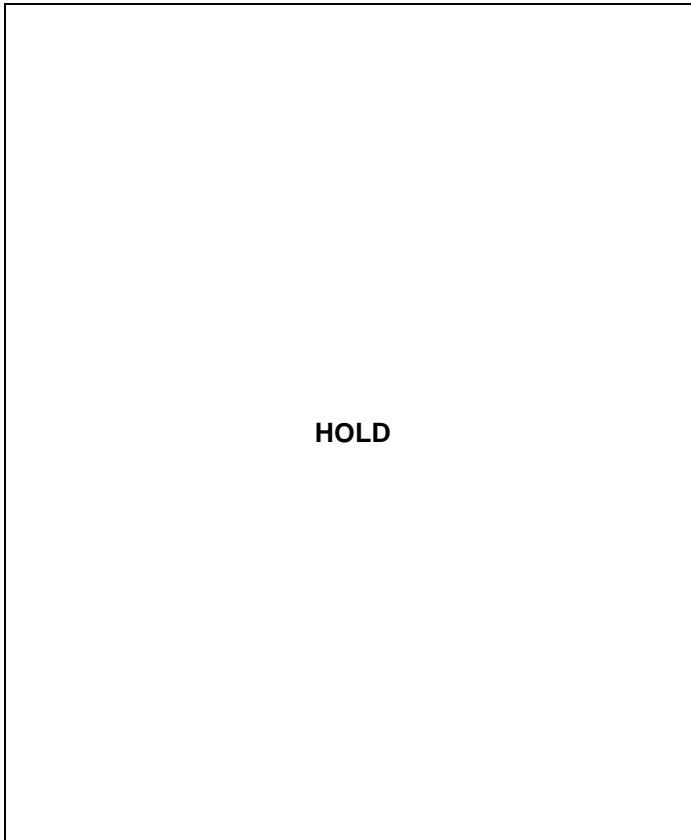| |
|---|
| **RELEASE FOR SUPPLY** |

What this label means:

THIS MANUFACTURED MATERIAL IS RELEASED FOR SUPPLY TO CUSTOMERS

➢ This label is applied by QA personnel (or trained warehouse personnel) after disposition (**approved for use or released for supply**) in the ERP system.

➢ These labels are automatically generated by the ERP system

➢ Goods can not be picked for dispatch to customer without Release for Supply labels applied

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1.9   Hold

HOLD

What this label means:

THIS MATERIAL IS ON HOLD AND MAY NOT BE USED or DISCARDED UNTIL DISPOSITION STATUS IS DETERMINED BY QA.

➢ This label is used to replace an Approved / Release for Supply / Approved for further processing label and is applied by QA personnel (or trained warehouse personnel). It is used where inventory already dispositioned as (**approved for use or released for supply**) in the ERP system has been deemed as not suitable for use or release (e.g. deviation, non compliance with specifications or GMP process). There may be a status change in the ERP system.

➢ These labels are generated using the labelview program

Pallet No. …………..

Item Code:	
Batch:	
Pallet Qty:	
MO No:	

Under Inspection