Standard Operating Procedure

Title: Raw Materials & Components - Incoming - Handling by Sampler

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EHS Statement

Follow any special instructions/precautions in Material Safety Data Sheets relating to material being sampled.

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Procedure

1. Receipt

On receipt of goods by the Receiving Store person, a Goods Receipt Slip (GRS Form-075) and Site ID Labels (Form-080) are printed for the consignment. Sampler has to collect the GRS, ID Labels and C of A from the receiving warehouse office. Ask for extra ID labels to warehouse personnel if needed for sampling of Printed components (SOP WAR-050).

2. Label Requirement

2.1. Site Identification Label

2.1.1. RAW MATERIAL (Actives and Excipients) – 1 label on each container.

2.1.2. IMPORTED FINISHED GOODS (i.e. Tablets) - 1 label on each container.

2.1.3. CHEMICALS – 1 label on each bag, jar, drum, etc. Do not place labels on lids of drums.

2.1.4. PRINTED CARTONS – 1 label on each container.

2.1.5. PRINTED PACKAGING MATERIALS – 1 label on each container.

Paper leaflets/PVC/Foil – have 1 label each roll.

2.1.6. PRINTED LABELS – 2 labels for each container – 1 on outside container and 1 on the top roll.
8. Appendix- Flowchart

Sampler to collect GRS, Site ID labels and C of A from the warehouse office

Check the labels are appropriate for the container

Check laboratory batch number is matching with the Identification labels.

Manufacturing lot number is matching with the GRS, ID labels, C of A and the manufacturer’s labels on the container.

Print a copy of Raw material Specification and Test Report for the corresponding raw material code. Write laboratory batch number on the form.

Transfer goods to Dispensary from Quarantine. Complete movement item 2 on the GRS form.

Sample according to SOP WAR-045, WAR-050, WAR-085 as appropriate

Attach sampled sticker (Sampled partial for Resampling) on the container.

Attach ID labels on the container

After sampling transfer goods to Quarantine. (Exception: Tablets). Complete movement 3 on the GRS.

Update GRS and Bin sheet for the remaining quantity after sampling

Raise a Deviation Report if any discrepancy found during checking

RE SAMPLING OF RAW MATERIAL FOR RE-TESTING

Receive a Raw material Sample Request Form and GRS number from the Laboratory