

Standard Operating Procedure

Title: Example-Raw Material Tablet Sampling By Dispensary

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PROCEDURE

1. Before Start to Sampling

- 1.1. Sampler to print out a blank [Raw Material Specification and Test Report \(TEM-005\)](#) for the corresponding raw material code number. Write down the Laboratory Batch Number on the RM Specification and Test Report.
- 1.2. Inspect containers and/or goods for any damage, if there is then notify Supervisor.
- 1.3. Prior to sampling goods, observe the relevant information from the **GRS** ([Form-075](#)) and notify supervisor of any discrepancies.
 - Material Number
 - Material Description
 - Supplier
 - Quantity
 - Number of containers
 - Manufacturer's Lot No.
 - Number of labels
- 1.4. On the RM Specification Form the following must be checked
 - Approved Supplier
 - Approved Manufacturer
 - Supplied Containers
 - Sampling procedure
- 1.5. For each of these the following information must be written on the RM Specification Form
 - Conforms
 - Initials
 - Date sampled
 - Quantity Sampled.

2. Tablet Sampling

- 2.1. Ensure the appropriate [Bulk Tablet Sampling Form \(Form-035\)](#) is printed and the required fields are filled in. There are different forms for each Raw Material Code.

Print and fill out one Tablet Sampling Form for each Lab. Batch number. Each IBC bin must contain only one lab number of tablets. Mixing of different lab numbers in one bin is not allowed.
- 2.2. **Precaution when sampling**

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4. Movement to Bulk Store or Reject Cage

- 4.1. Laboratory analyst will advise the warehouse staff whether a shipment of Tablet is released or rejected after a laboratory test. In either case laboratory will produce Released or rejected stickers respectively one for each container.
- 4.2. If the shipment is released for production use, the warehouse staff will attach all released stickers on to each container under laboratory test. Warehouse staff will check available storage bin in the Bulk Store for the designated raw material or component types. Move the released pallets from storage bin in Quarantine to Storage bin in the bulk store and update the movement item **4 on the GRS**.
- 4.3. In the case the shipment is rejected, warehouse staff has to raise a [Deviation Report \(QMS-035\)](#) and send to Quality Assurance Department. Attach the rejected stickers immediately onto each container involved and transfer the pallet/s in the reject cage. A comment should be made on the **GRS** regarding the rejection and inform the purchasing team.
- 4.4. The Reject stickers are placed on all sides of all containers of the rejected material in prominent positions.

5. Re-sampling of Tablets for Re-testing

A Laboratory request to resample of tablets is sent to the Samplers via a sample request form (**Form-010**) and GRS number. Sampler to:

- Collect the original GRS for the material from warehouse office.
- Write the adjusted quantity after re-sampled on the copy of **GRS**.
- Write the re-sampled details in the **Raw material/component sampling log book** (See section 3).
- The container is marked with a “**Sampled Partial**” ([Form-100](#)) sticker and the **Bin Sheet** is adjusted again.
- The Sampler then returns the adjusted copy of **GRS** with the physical sample to the Lab.
- The **Sample Request Form** is kept in the dispensary office. The adjusted **GRS form** is kept in warehouse and use to update the inventory stock.

6. Summary of Changes

Version #	Revision History
WAR-080	New

End of Procedure