

Standard Operating Procedure

Title: Sampling of Raw Materials

Department	Warehouse		Document no	WAR-045	
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Document Owner

Warehouse Manager.

Affected Parties

All warehouse staffs working as a sampler.

Purpose

To describe schedules and safety precautions for sampling of Raw Materials and secondary reference standards.

Scope

The procedures covered in this SOP are the responsibility of the following:

- Sampler
- Dispensing Sampler
- Laboratory Staff

Definition

RM. Specification and Test Form	Part of a master document containing sampling requirements, testing requirements, specifications and control methods used for a particular RM.
Raw Mat. Sampling Log	Log book kept in dispensary where attributes of all goods sampled are entered
Laminar flow	Nonturbulent flow of air in layers, flowing in a vertical direction in the case of a bio-safety hood)
Sampling Labels	Labels applied to identify jars in which samples are kept.
Secondary Standard	A sample material that can be used as a secondary measure for calibration, and provides a stable reference that is repeatable.
Sample cupboard	Designated cupboard areas where raw material sample jars/containers are kept.
Lab sample	Sample as per RM Specification form for laboratory analysis
Micro status sample	Sample as per RM Specification form for microbiology analysis
Outside testing	Sourcing outside contract laboratory for doing the testing.

Related documents

Form-010	Sample Request Form
TEM-005	Raw Material Specification and Test Report
Form-105	Sampling Labels
Form-090	Sampled Sticker

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- 1.2.5. Only an appropriate vacuum pump device is to be used for sampling liquids stored in drums. A new tube must be used for each chemical and the plastic container must be cleaned thoroughly and sterilised with IPA 70% between each chemical sampled.
- 1.2.6. All containers must be resealed immediately they have been sampled. Bags that have been opened are sealed with tape and placed inside a re-sealable plastic bag. Drums and bottles must be resealed tightly to ensure product is kept airtight.
- 1.2.7. A '**SAMPLED**' sticker must be attached to the specific containers from which samples have been taken.

2. Sampling Procedure

2.1. Chemicals

- 2.1.1. All containers to which samples will be kept bear a Sampling label. Transfer the sample using the appropriate tool/s to the sample jar/s, which has been clearly labelled on the body of the jar (NOT on the lid), with the following:
 - Product
 - Product material code
 - Product Lab. No.
 - Number of samples.
- 2.1.2. The amount of sample required is stated in the **Raw Material Specification Form** in the "sampling Requirement" section. In addition to Lab samples, Micro sample, sample for Outside Testing may be required. These are composite samples (taken from all containers) combined into the necessary amount of jars. .
- 2.1.3. "**SAMPLED**" stickers must be applied to the container from which the sample is taken, noting the Date, Sample Qty and New Quantity.

3. Example – Tablet Sampling (Refer to SOP WAR-080)

- 3.1. All imported Tablets are sampled as per the **Raw Material Specification Form**.
- 3.2. **Site ID labels** are placed on every container next to the Manufacturer's label.
- 3.3. Check all containers for Manufacturer's Batch Number.
- 3.4. ****Precaution when sampling.**** Some of the tablet bags contain a small silica gel bag inside to keep out the moisture. This is placed on the top of the tablets inside the tablet bag. The bag must be cut as follows:
 - 3.4.1. Pinch tablet bag to form raised section for cutting.
 - 3.4.2. Make a small cut to ensure that the silica gel bag was not cut.
 - 3.4.3. While continuing to pinch the tablet bag, continue the cut so that the tablets inside may be taken for samples.

4. Secondary Standards

This sample will be an additional sample to the usual sampling performed.

- 4.1. Samplers receive a Sample Request Form (**Form-010**) for required secondary standard sampling from the Laboratory.