

Standard Operating Procedure

Title: Sampling of Raw Materials in Sampling Booth

Department	Warehouse	Document no	WAR-100
Title	Sampling of Raw Materials in Sampling Booth		
Prepared by:		Date:	
Checked by:		Date:	
Approved by:		Date:	

1.0 DOCUMENT OWNER

Warehouse / Quality Manager

2.0 PURPOSE

To outline acceptable sampling booth operating parameters and required actions prior to, during and after completion of sampling of Raw Materials in the receiving area sampling booth at the GMP site.

3.0 SCOPE

The scope covers sampling of Raw Materials (RM), [Active Pharmaceutical Ingredients](#) (API) and Semi Finished Goods (SFG).

4.0 RESPONSIBILITY

4.1 Sampling of RM, API and SFG in the sampling booth can only be carried out by operators trained in sampling (Sampling Inspectors).

4.2 Sampling is carried out in the sampling booth only if conditions are within acceptable operating range (refer Step 5.2 below).

4.3 Only one lot of one item can be sampled at any one time.

4.4 The sampling booth is a GMP enforced area and clothing and Jewellery policies apply (refer SOP [MAN-005 Clothing Requirements Inside the Factory Area](#)). Applicable safety and breathing protection devices are used (refer SOP [EHS-100 Personal Protective Equipment \(PPE\) policy](#)).

4.5 Aseptic sampling is first carried out (where applicable), followed by Chemical sampling of any given lot. NIR samples are then drawn from chemical samples after the containers of sampled lots are removed from the sampling booth.

4.6 Cleaning activities are carried out (refer SOP [WAR-105 Cleaning of Sampling Booths](#) and Implements in the Raw Materials Quarantine Store) and Logbook entries are made in the Equipment and Module Logbook.

4.7 All instrumentation in the sampling booth should have valid calibration stickers. Engineering is contacted if any instrument needs calibration. Sampling is suspended till calibration is performed.

4.8 In relation to number of samples required, refer SOP [WAR-085 Sampling and Inspection of Raw and Bulk Materials](#). In relation to selection of respirator, refer [SOP EHS-140 Respiratory Protection Program](#).