1.0 DOCUMENT OWNER

Warehouse / Quality Manager

2.0 PURPOSE

This procedure outlines the procedure for cleaning the sampling booth in the receiving quarantine area at the GMP site.

3.0 SCOPE

This SOP covers the cleaning of the quarantine-area sampling booth which is used for sampling Raw Materials, Active Pharmaceutical Ingredients, Bulk materials / Semi-finished goods and primary packaging materials.

The scope of this SOP covers cleaning between samplings and weekly cleaning by the QA Sampling Inspectors in the warehouse and also cleaning during every working day by plant cleaning staff.

4.0 RESPONSIBILITY

4.1 Only trained QA Sampling Inspectors may operate the sampling booth and conduct sampling of inventory items in the sampling booth.

4.2 All sampling, cleaning and maintenance activities in the sampling booth are recorded in the logbook provided at the entrance to the sampling booth.

4.3 The sampling booth must always be clean and made ready for use after every sampling activity by the QA Sampling Inspector. The plant cleaning staff must do the cleaning after any major maintenance activity in the sampling booth. Cleaning status must be displayed at the door on the status board that is provided.

4.4 The Stainless steel vents in front of the pre-filters in the sampling booth should be cleaned once a week by the QA Sampling Inspectors.

4.5 Plant cleaning staff shall clean the sampling booth towards the end of every working day in accordance with SOP MAN-015 “Factory Cleaning Procedure” and use approved sanitizing agents.

4.6 Dedicated vacuum cleaner fitted with HEPA filter, 70% alcohol in spray bottle, lint free disposable cloth and S4 waste bin are utilized by QA Sampling Inspectors whilst carrying out cleaning between sampling and weekly cleaning.

4.7 All sampling instruments are cleaned in the wash bay in the manufacturing area using approved cleaning agents available in the area.

4.8 All cleaned sampling implements are sealed in plastic bags with approved stickers with cleaning dates. These bags are kept in the sampling cupboard in the quarantine area in the warehouse.