

Standard Operating Procedure

Title: Cleaning Responsibilities and Methods for Employees

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Document Owner

Operations Manager

Affected Parties

All Site Colleagues

Purpose

To specify responsibilities of Manufacturing Staff in the cleaning of machines, equipment and the area around the machines.

Scope

The purpose of cleaning is to prevent contamination of product by foreign materials from another batch, or by dirty parts, which may contain bacteria. It also removes debris, which may interfere with smooth operation of machines.

It is the responsibility of all Manufacturing Staff to follow this SOP.

Definition

HEPA	High Efficiency Particulate Air (filter)	
Cleanroom	Environmental Grade B & C area	
Sterile	Free from micro-organisms	

Related Documents

Form-135	Pest Sightings Report
EHS-015	Waste Removal Process
MAN-005.	Clothing Requirements Inside the Factory Area
MAN-015	Factory Cleaning Procedure
QMS-035	Deviation Report System

EHS Statement

Safety glasses and gloves must be worn when using compressed air during cleaning and when using IPA/solvent.

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Several of these bucket mop trolleys are available throughout the factory and they should remain **dedicated** to the particular areas.

3.2. **Dustpans**

Their use is necessary especially for spilt glass, but not ideal as dust may be generated. Squeegees are used in place of brooms.

3.3. Vacuum Cleaners with HEPA filters

These are preferred for picking up dust from the floor or from containers. Compressed air hoses are to be used only in specific areas where access to cleaning is difficult as it may spread contamination e.g. inside blister packers. Safety glasses must be worn when using compressed air.

3.4. 'One Touch' disposables Wipes

These are SINGLE-USE cloths for wiping operations and are to be discarded after use. Sterilised Wipes are used in Sterile areas.

3.5. Lint-free Absorbent Wipers

These are available in Sterile for wiping around vessels and filling equipment and avoiding contamination with fibres.

3.6. Other devices

Nylon scouring pads - NOT steel wool

Bottle brushes

Plastic scrubbing brushes

"Tacky" mats

"Purity" wipes (lint free disposable)

4. Solutions to be used for cleaning

- 4.1. General-purpose detergent/bactericide used in mop buckets and for general disinfection.
- 4.2. **70% IPA** <u>Filtered</u> Isopropyl alcohol (IPA).Used for cleaning/sanitising of working surfaces of machines and for spraying items in airlocks, in transit to sterile areas. This solution is also sprayed onto gloved hands to sanitise them after touching walls, equipment, etc., inside sterile areas.
- 4.3. **Distilled Water** Freshly collected. For rinsing glassware and tubing; also removing spilt, dried product from machines.
- 4.4. Antiseptic hand cleaning solutions.
- 4.5. Other Ink Solvent or thinner for ink removal.

NOTE: <u>Normal Detergents are NOT used in the Factory</u> as traces are difficult to remove from equipment. **ONLY NEUTRAL DETERGENTS MAY BE USED**.

5. Rubbish Removal

Rubbish is segregated and disposed of in different ways. It is to be removed from the factory area on at least a daily basis.