

Department	Environmental, Health and Safety	Document no	EHS-045		
Title	Building Cleaning Procedure				
Prepared by:		Date:		Supersedes:	
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Approved by:		Date:		Review Date:	

1.0 AFFECTED PARTIES

All Environment, Health and Safety personnel

2.0 PURPOSE

This SOP provides an overview of the procedures used for the contract cleaning and sanitation of the GMP building, Engineering shed and Demountable buildings. The SOP defines the areas and responsibilities for the contract cleaners.

3.0 SCOPE

This SOP lists the overall cleaning policy / procedures for the internal building structure, offices, production rooms, etc. The SOP includes all areas of the building, both GMP and non-GMP areas.

The SOP does NOT relate to the cleaning of machinery, equipment or tooling related to the production process.

4.0 RESPONSIBILITY \ BUSINESS RULES

4.1 Responsibility

It is the responsibility of the EHS Building Services Team to provide trained cleaners for the designated areas of the building. All cleaners must ensure the following rules are understood and maintained at all times and not cause

4.2 Cleaning Agents

All cleaning agents / chemicals used for cleaning must be approved by Quality and must be listed on the current "Approved List for Lubricants, Cleaning Agents, Oils and Miscellaneous Materials"

Non-approved agents / chemicals are NOT permitted inside the building and must be quarantined in the Engineering shed until approved for use.

Adequate segregation must also be provided to protect 'Product' from contact with stored cleaning agents.

Any new cleaning agents must be introduced via Change Control.

4.3 Cleaning Staff

Only GMP trained cleaners are permitted to clean GMP production areas and sign GMP area cleaning records. Non-qualified cleaners are not permitted to sign module or room logbooks.

Non-qualified cleaning staff may only be used in GMP production areas under the direct supervision of a qualified cleaner for training purposes.

4.4 Cleaning Documentation

Adequate documentation records must be maintained for all cleaning activities performed and areas cleaned.

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5.1.1.6 Modified procedures for “wet” cleaning operations (safety reasons), i.e. use of shoe covers or laying down of towelling (to capture any water) at the entry to the room, while wet cleaning takes place inside the room.

5.1.1.7 Any clothing soiled during cleaning operations is to be changed before the next cleaning task.

5.1.2 Cleaning Measures

5.1.2.1 All equipment used to clean any product, chemical or soil from a room, product spill or general cleaning must not be reused for any other purpose or cleaning activity until the equipment has been thoroughly re-cleaned and sanitized.

5.1.2.2 After sanitising, equipment must be allowed to air dry before reuse to enable the sanitising agent to effectively kill bacteria.

5.1.2.3 All equipment used is to be stored in clean conditions and maintained in a visibly clean and good condition.

5.1.2.4 Clean mop heads must be stored in labelled, sealed [clean and sanitised](#) containers and stored in a separate area from dirty or used equipment awaiting cleaning.

5.2 Areas and Responsibilities

5.2.1 Contract Cleaners

The contract cleaners are responsible for maintaining adequate cleaning and sanitation to the following areas:

- Manufacturing Area – excepting Granulation and Blending rooms
- Pharmacy and Quarantine sampling booths (Daily)
- Pharmacy and Quarantine storage areas
- Blister Rooms and Packaging Area
- Wash bays and equipment storage rooms
- Laboratory (both levels)
- All office areas
- Packaging, Semi-Finished Goods and Finished Goods Warehouse
- Building Amenities and Waste disposal area

5.2.2 Production Operators

Granulation and Blending areas are maintained by operators due to the safety risks associated with the active ingredients used in the blends. Core Area operators have the appropriate training and safety equipment to clean these rooms.

All machinery and equipment used in both Manufacturing and Packaging areas is again maintained and cleaned by production operators.

5.2.3 Workshops and Plant Rooms

Receiving, Engineering workshops and plant rooms areas are maintained under the general housekeeping procedures with assistance from the cleaners for hard floor sealing and roof and wall cleaning (i.e. no equipment or bench cleaning).

5.3 Type of Cleans

Four types of cleans are used for the West Ryde Facility. They are:

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5.6.1 Core Area Clean Zone (All rooms) use RED ONLY equipment.

5.6.2 Packaging Hall (Vinyl floor area) use BLUE ONLY equipment.

5.6.3 Laboratory (Both levels) use YELLOW equipment.

5.6.4 General use (All other areas) use GREEN equipment.

Additional measures introduced include:

5.6.5 Core and Packaging area equipment is washed, sanitised and stored, off the floor, in dedicated cleaners wash / store rooms (i.e. equipment stays inside the clean zone).

5.6.6 Mop heads for the Core and [Packaging Areas](#) are both stored and washed separately from all other mops used anywhere in the factory.

All cleaning equipment is supplied by and remains the property of the Contract Cleaning Company. Equipment is to be well maintained and replaced as required.

Any equipment borrowed from the cleaners must NOT be placed back in storage after use until it has been cleaned and re-sanitised by the cleaners. Equipment MUST also be suitable for the specific area in which the equipment is to be used and returned to the relevant wash bay.

5.7 Cleaning and Disinfectant Agents

5.7.1 Only approved chemical agents can be used inside the manufacturing building.

5.7.2 All containers of approved cleaning agents inside the building must be stored separately from product and have a green "Released" sticker attached.

5.7.3 A list of approved chemicals can be found in the Approved List for Lubricants, Cleaning Agents, Oils and Miscellaneous Materials.

5.7.4 Copies of current MSDSs for all cleaning agents used must be displayed in all cleaner's rooms for quick and easy access in the event of a spill.

Note: MSDSs are current for 5 years.

5.7.5 New chemicals or new formulations of existing chemicals cannot be used until approval and acceptance is granted in accordance with the procedure for Change Management System.

5.7.6 Any chemicals received, which are not on the approved list should be immediately quarantined in the Engineering building and not used until the Change Request has been approved for the new chemical.

5.7.7 All chemical containers must be clearly labelled and hazard information displayed if appropriate for the chemical.

5.7.8 Chemical dilution ratios must be clearly displayed and measuring equipment available in each cleaner's room.

5.8 Cleaner Accreditation and Training