

Standard Operating Procedure

Title: Personal Hygiene, Jewellery and Clothing Policy

Department	Quality Management	Document no	QMS-160
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1.0 DOCUMENT OWNER

Technical/Quality Manager

2.0 PURPOSE

The aim of this policy is to outline GMP requirements for personal hygiene, clothing and jewellery for all colleagues (employees, visitors and contractors) entering a GMP site.

3.0 SCOPE

3.1 This procedure applies to all colleagues, (i.e. all employees, casual / contract or permanent), contractors and visitors entering the GMP facility.

3.2 Clothing, jewellery and personal hygiene requirements for all colleagues are defined in this procedure.

3.3 This procedure is applicable to the GMP facility, incorporating Manufacturing, Packaging, Pharmacy, Airlocks, Warehouse, Dispensing and Laboratory areas.

4.0 RESPONSIBILITY \ BUSINESS RULES

4.1 It is the responsibility of all colleagues to adhere to the procedures listed in this SOP.

4.2 It is the responsibility of the host of all contractors and/or visitors entering the site building to ensure that they comply with this policy.

4.3 It is the responsibility of all colleagues who either work in or visit the Clean Zone to comply with this procedure. 'Clean Zone' is defined as an area within packaging/manufacturing (including the pharmacy dispensing area) which requires some form of gowning.

4.4 It is the responsibility of all people entering the building to ensure that [Personal Protective Equipment](#) (PPE) and clothing is worn in areas as indicated by the signage directly outside the various work areas and/or as required by any 'Work Method Statements or Plans' used for specific contracted works.

4.5 It is the employee's responsibility to ensure jewellery is kept safe. Site authority takes no responsibility for loss of jewellery as a result of this policy.

4.6 Food and drink in this policy means all food and drink, including but not limited to lollies, chewing gum, cigarettes, tea, coffee and soft drinks.

5.0 PROCEDURE

5.1 Clothing Policy – General Rules

5.1.1 Hair covers must be worn in the Packaging Hall, [Warehouse Sampling](#) Booth and the Manufacturing Area / Clean Zone. They must cover the ears and all hair.

5.1.2 Beard covers must be worn in the Packaging Hall, Warehouse Sampling Booth and the Manufacturing Area / Clean Zone if colleagues have facial hair – this includes beards,

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5.2.2 All colleagues must wash their hands with the anti-microbial soap / solution provided and dry them prior to and after meal breaks and after using a toilet.

5.2.3 For colleagues who may have contact with exposed product (i.e. in Packaging and in the Clean Zone), the following rules apply:

- Colleagues' fingernails must be trimmed and clean. No false nails or nail polish may be worn.
- No jewellery apart from a smooth wedding band may be worn. This must be covered with tape prior to entry into the [Packaging area](#) / Clean Zone or Warehouse Sampling Booth. No jewellery must come into contact with exposed product.
- No makeup or false eyelashes may be worn.

5.2.4 No food or drink or personal medication may be consumed or stored in Manufacturing / Clean Zone / Packaging / Warehouse / Laboratory areas.

5.2.5 The consumption and storage of food, drink and personal medication is prohibited throughout the Manufacturing building and Engineering building with the following exceptions:

- Short-term storage of food and drink is permitted in the change rooms off the foyer, in the lab entrance area and in the offices on the upper floor of the Manufacturing building, provided that food/drink is stored in suitable containers that prevent dropping of food scraps or spillage of liquids.
- Water may be consumed in the areas of the Manufacturing building where water coolers are provided, with the provision that all associated rubbish be removed or placed in the appropriate receptacles provided.

5.2.6 A sign is placed on the automatic doors prior to the entry to the Manufacturing and Warehouse areas in the Production building indicates that no food or drink is permitted beyond that point.

5.2.7 Site colleagues working in the Demountable are not subject to the restrictions in this SOP when in the demountable but must adhere to this policy when in the Manufacturing building or Engineering building.

5.2.8 Any organized function involving food and/or drink must be organized to occur outside the Manufacturing building or Engineering building.

5.2.9 Sales of charity lollies for fundraising, etc., must be conducted [outside the Manufacturing Plant](#) or in the areas where goods may be stored.

5.3 Company Health Practices

5.3.1 All colleagues should receive a medical examination upon recruitment. After the first medical examination, examinations should be carried out when necessary for work and personal health.

5.3.2 Colleagues or contractors with a communicable disease (e.g. cold or flu) must advise their Team Leader if working in close vicinity of exposed raw materials or product. The site authority reserves the right to reassign the duties of colleagues with communicable diseases.

5.3.3 Colleagues or contractors with open lesions, cuts etc on exposed surfaces of the body must report to the Team Leader before taking up or resuming duties. All such lesions, cuts etc must be covered with sterile non-permeable dressings, e.g. Band-aids.

5.4 Production Area – Gowning

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5.5.3 Movements between the Core Manufacturing Area and the Packaging Area should be via the Packaging/Manufacturing Corridor. The glass doors at the packaging lines should not be used to access the Core Area Corridor or vice versa.

5.6 Production Area - Transport of Materials

5.6.1 All goods entering the Core Manufacturing Area must be stored on a clean plastic or metal pallet. Wooden pallets may be used in other areas.

5.6.2 Materials delivered to the Production Area are taken into the Core Area material transfer airlock by means of a forklift or pallet truck. This airlock is used for the transportation of materials only and should not be used as a walkway for personnel. The materials are then collected by personnel from within the airlock by means of a pallet truck or forklift designated for use inside the clean zone area only.

5.6.3 Goods for removal from the Clean Zone are deposited in the airlock by means of a pallet truck or forklift and are collected by personnel from the outside area for transportation to their destination.

5.7 Pharmacy

5.7.1 The Pharmacy Clean Zone includes the weighing room, the weighing room air lock, the change room, the dispensed job staging area, and the air-conditioned portion of the raw material store. The change room for this area is off the air lock between the weighing room and the storage rack area. Colleagues in this area must wear a disposable Tyvek suit or grey uniform (**Figures 3 and 4**).

5.7.2 Upon exiting the Clean Zone, colleagues must change out of the Tyvek suit or grey uniform.

5.7.3 Colleagues in other areas of the Pharmacy must wear clothing in line with Production Area requirements (**Section 5.4**) as a minimum. Should access to the Clean Zone be required, clothing requirements apply (**Figures 3 and 4**). White cotton overalls should be used where appropriate depending upon the work to be undertaken (**Figure 5**).

5.8 Warehouse – Sampling Booth

5.8.1 Colleagues must wear a disposable Tyvek suit or grey uniform, safety shoes and disposable shoe covers (**Figures 6 and 7**). This clothing must be put on whilst inside the sampling booth (including when cleaning the sampling booth) and before any raw material container is opened.

5.8.2 The Jewellery Policy as outlined in **Section 5.2** applies to the Warehouse Receiving Dock Sampling Booth.

5.8.3 Upon exiting, colleagues must change out of the Tyvek suit or grey uniform.

5.8.4 Warehouse colleagues must wear a site issued uniform that includes a yellow fluorescent top or vest and safety shoes.

5.8.5 Any visitors entering the warehouse area must wear a fluorescent yellow vest, with the word 'Visitors' printed on the back (**Figures 8 and 9**).

5.8.6 Appropriate breathing apparatus/dust mask and/or glasses are to be used in the Warehouse Sampling Booth.

5.9 Laboratory (Chemistry and Microbiology)

5.9.1 Laboratory white coats must be worn before gaining access to the Laboratory areas (see **Section 6** for a definition of the Laboratory) (**Figure 10**).

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** Hair to be contained neatly

*** Must be worn when working with autoclave, preparing or pouring media or when handling glassware.

6.0 DEFINITIONS / ACRONYMS

6.1 Definitions

Clean Zone:

This zone consists of the airlocks, Core Area, Packaging area, all associated corridors and the Dispensary Pharmacy.

Contractors / Service Providers:

Colleagues who are contracted and approved to perform some work on site within the manufacturing facility. An example is a contractor who comes on site to fix or service machinery.

Laboratory:

Areas within either the Chemistry or Microbiology Laboratories including the laboratory bench top areas, instrument rooms and laboratory wash bays.

Laboratory – Other Areas:

Areas including the offices of the managers and supervisors/team leaders, the entrance foyer, and the mezzanine filing area.

Production Area:

This consists of the airlocks, Core Area and associated corridors, and the Packaging Area.

Visitors:

In this document, the term 'Visitor' is used to describe a person who does not routinely work within the production building. Examples include visitors on tours who will not be touching or interfering during the manufacturing process.

Transit Areas:

Area including the corridor between the entrance foyer and the packaging airlock change room and the downstairs offices.