

ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements (TM/HS)

CHAPTER 4 – SANITATION AND HYGIENE



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Approved by:

ASEAN TMHS GMP Task Force

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OUTLINE

- Principle
- Personnel:
 - Practice of Good Personal Hygiene
 - Training of Good Personal Hygiene
- Premises
- Equipment and Utensils



PRINCIPLE

- A high level of sanitation and hygiene shall be practised in every aspect of the manufacturing of TM/HS.
- The scope of sanitation and hygiene covers personnel, premises, equipment and utensils; in fact, anything that could become a source of contamination to the product.
- All employees shall be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the quality of products.







PRINCIPLE

Taking necessary precautions to protect components, TM/HS products and contact surfaces against the contamination of:

- micro-organisms
- filth
- other extraneous materials

Particle generation from one person per minute



	448,000	142,000	14,920
	4,450,000	462,000	48,600
	2,240,000	390,000	31,700
	5,380,000	1,285,000	157,000

According to:

Takasago Thermal Engineering Co – Fläkt



SANITATION

Hygienic control on manufacturing processes, including personnel, premises, equipment and handling of materials [from starting materials to finished products].



HYGIENE

Conditions and practices that help to maintain health and prevent the spread of disease



PERSONNEL

Type of Contaminant



Microorganism:
Bacteria, fungi, yeast
and mold.



Particulate:
All particle which are
not part of the product
component, such as
filth, glass fragment,
fiber, hair, metal.



Extraneous Materials:
Lead to cross
contamination, mixed
up and false

EXAMPLE

Particle generation from one person per minute



	448,000	142,000	14,920
	4,450,000	462,000	48,600
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According to:
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PERSONNEL

All personnel, prior to employment shall undergo health examinations. During the course of their employment they shall also routinely undergo health examinations which shall include relevant examinations appropriate to the tasks that they are required to perform.

- E.g. General health examination for all personnel
- Eye examination for all personnel



PERSONNEL

Procedure and record of personnel hygiene for employees who perform manufacturing processes should be available :

Annex 1 - SOP on Personal Hygiene

Annex 2 - Record Daily Inspection on Personal Hygiene

Annex 3 - General Health Examination

Annex 4 - Employee Illness Report Form



PERSONNEL

All personnel shall practice good personal hygiene. They shall be trained in the practices of personal hygiene. High level of personal hygiene shall be observed by all those concerned with manufacturing processes.

Training

- Appropriate practices in personal hygiene
- Related written procedure and instructions



PERSONNEL

Personal Hygiene

Refers to cleanliness of a person's body against

- Disease causing microorganisms
- Filth/dirt
- Extraneous materials



PERSONNEL

Some examples to maintain Personal Hygiene

Bath/Shower

Wash off dead skin cells and disease-causing microorganisms

Brush teeth

Clear up the food residue which are source of microorganisms

Wear clean working clothes (uniform), gloves and footwear

Clothes, gloves and footwear can carry bacteria into the premises

Keep fingernails clean, trimmed and without polish

No artificial nails

(Polish or artificial nails can fall off)



PERSONNEL

Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products shall not be allowed to handle raw materials, packaging materials, in-process materials, and finished products until the condition is improved.





PERSONNEL

Hand Washing

Direct contact shall be avoided between the operator's hands and , raw materials, intermediate or , bulk product.

Proper washing of hands and wearing of gloves shall be used if contact with hands is unavoidable.





PERSONNEL

Hand Washing

Ensure that the hands are washed properly before entering the production areas and rewashed or have the gloves changed when contaminated





PERSONNEL

Hand Washing

- After using the toilet
- After touching bare body parts (skin)
- After coughing, sneezing, using a handkerchief or tissue
- After consuming food , drinking, smoking
- Before entering/returning to manufacturing areas





PERSONNEL

How to wash your hand





PERSONNEL

Use of Gloves

Gloves are used to protect materials and products from directly contacting bare hands

- Hands should be washed properly and thoroughly before putting gloves on
- Minor cuts, scrapes, etc. should be covered with an approved bandage prior to putting on gloves





PERSONNEL

Protective garments

Assure protection of the product from contamination as well as the safety of the personnel, appropriate protective garments shall be worn. Soiled uniforms shall be stored in closed containers until properly laundered.





PERSONNEL

Appropriate protective garment (uniform)

Ensure that clean uniform, footwear and hair covers are sufficiently provided to all production employees

Ensure that clean, dedicated uniform, footwear and hair covers are worn when entering the manufacturing area.



Overall Suit



Two Piece Suit



PERSONNEL

Appropriate protective garment (uniform)

To prevent hair from falling into materials, products and equipment, hair net and effective hair restraints must be worn.

- Hair net should be of appropriate quality to contain hair and be replaced when damaged or worn out
- All hair must be tucked inside the net
- The net should be sufficiently large to cover both ears
- Wear beard net (where applicable)





PERSONNEL

EXAMPLE

Appropriate protective garment (uniform)



Production Coverall



Bouffant Cap/ Hair Net



Shoe Cover



Gloves



PERSONNEL

Only authorised personnel shall be allowed to enter production areas.

Visitors or untrained personnel shall, preferably, not be taken into the production and quality control areas.

If this is unavoidable, they shall be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They shall be closely supervised.





PERSONNEL

Smoking, eating, drinking and chewing or keeping of plants, food, drink, smoking materials and personal medicines shall be restricted to specific areas and not permitted in production, laboratory, storage or other areas where they might adversely influence product quality.

A separate dedicated area for eating shall be provided outside the production area.

Personnel medicines should be stored in the individual locker to avoid false and/or mixed up during production process



PERSONNEL

The wearing of makeup, wrist watches and jewelry shall be prohibited in the production area.

However for jewelry or objects that cannot be removed; it must be covered by material (e.g. gloves) that is maintained in an intact, clean and sanitary condition.





PREMISES

Sanitation of Premises

Premises used for the manufacturing of products shall be of suitable design and construction so as to facilitate good sanitation.

Ensure that the premise is neat and clean and is free of puddled water.

Floorings of the equipment washing rooms could be sloped to allow draining of water





PREMISES

Hand washing and well ventilated toilet facilities and changing rooms shall be provided for personnel at suitable locations.





PREMISES

Suitable locker facilities shall be provided at appropriate locations for the storage of employees clothing and personal property.





PREMISES

The preparation, storage and consumption of food and beverages shall be restricted to specific areas, such as meal rooms and canteen.

Facilities in such rooms must meet sanitary standards.

Meal rooms and canteen rooms shall not have direct access to controlled areas (e.g. production area and areas use to store materials used for production and finished products).



PREMISES

Waste material shall not be allowed to accumulate. It shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals.



Ensure that there are no harborages and breeding areas for pests at the site

Ensure that properly closed areas are used for storage of waste materials





PREMISES

Rodenticide, insecticides, fumigating agents and sanitizing materials used must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products. There shall be a pest control programme, documents such as layout, trending and expectations.

Contract agreements shall be established, where applicable.

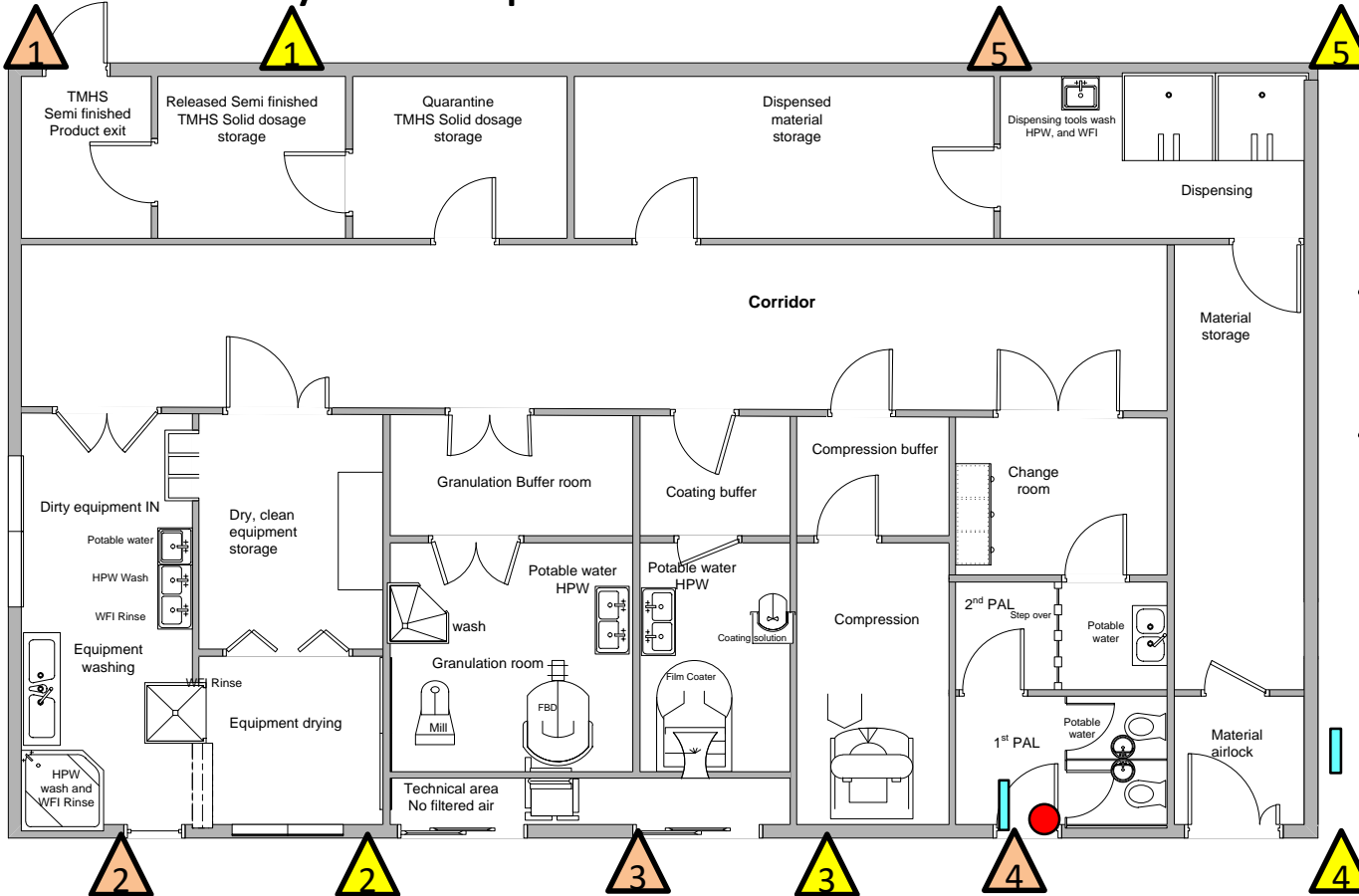
- Annex 5 - Sample of Pest Control Inspection Record
- Annex 6 - Sample of Pest Control Monitoring Record
- Annex 7 - Sample SOP on Pest Control





PREMISES

Layout of pest and insect control in Processing Area



EXAMPLE

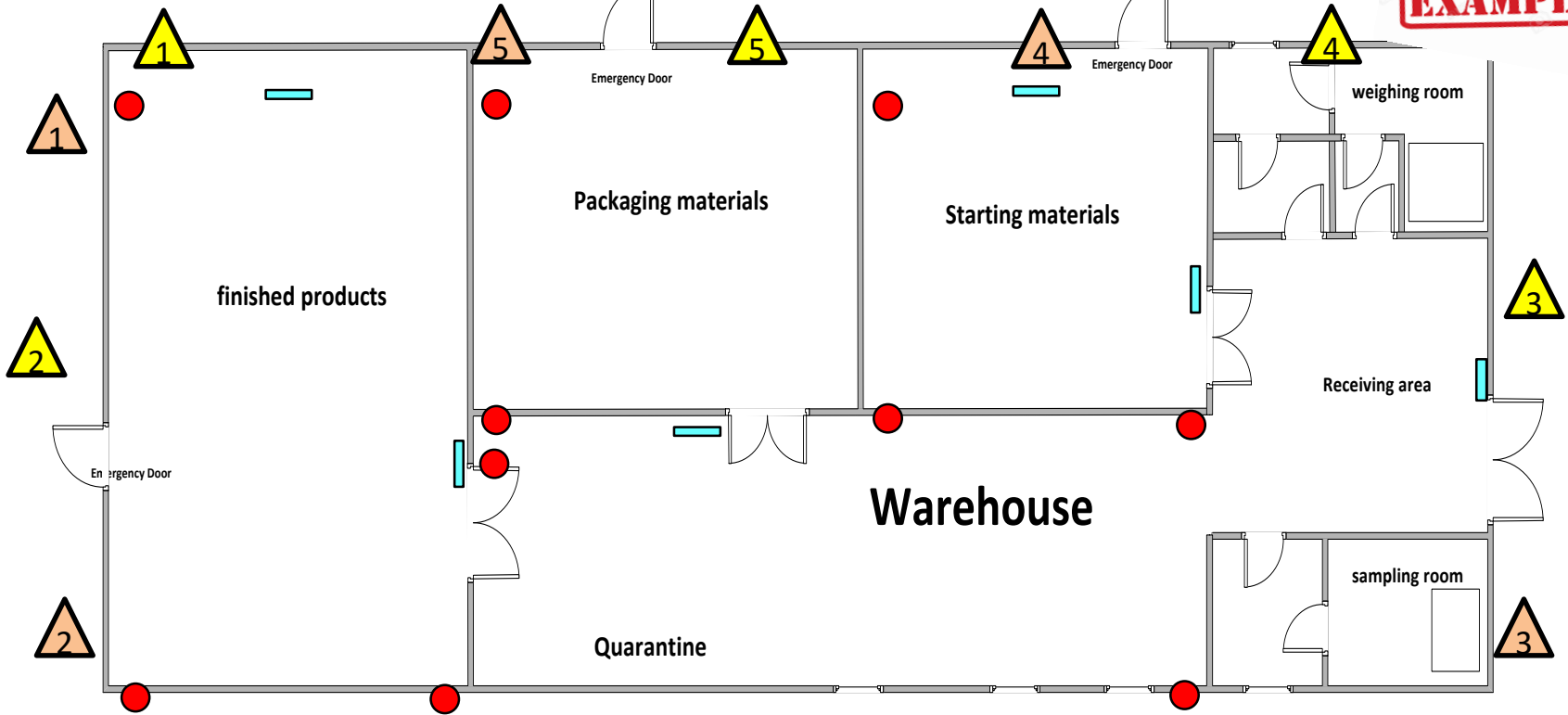
- = Bait stations First rotation
- = Bait stations Second rotation
- = electric insect eradicators
- = Mechanical traps



PREMISES

Layout of pest and insect control in Warehouse

EXAMPLE



= Bait stations
First rotation

= Bait stations
Second rotation

= electric insect
eradicators

= Mechanical traps



PREMISES

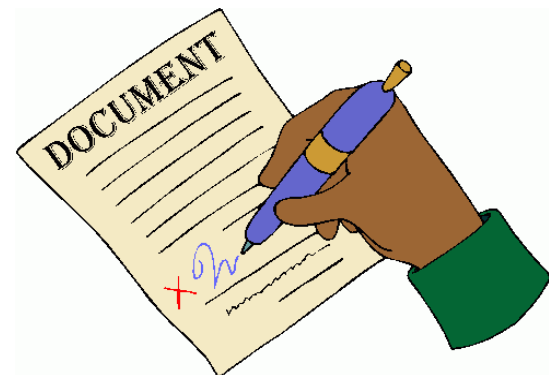
There shall be written procedures assigning responsibility for sanitation and describing cleaning schedules, methods, equipment, materials to be used and facilities to be cleaned in sufficient detail. Such written procedures shall be followed and the result shall be documented.

Annex 8 - SOP on Cleaning of Equipment and Accessories

Annex 9 - Cleaning Schedule Form

Annex 10 - Cleaning Record Form

Annex 11 - Cleaning Inspection Record





PREMISES

Pets are not allowed within the vicinity of the manufacturing plant.





EQUIPMENT AND UTENSILS

Equipment and utensils shall be cleaned both inside and outside after use according to established procedures. Cleaned equipment shall be kept or stored in a clean condition and identified with the status of cleaning, and checked for cleanliness prior to each use.



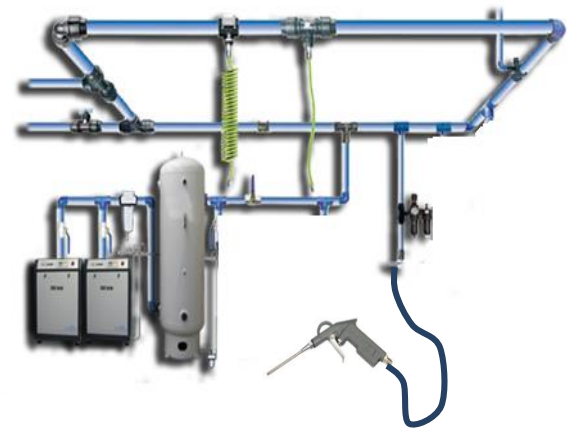
CLEANED	
Machine/Equipment Name.....ALCO Filling 02.....	
Product Name <u>AAAAA</u> Lot <u>123</u>	
Cleaned by <u>Sonchai</u> Date <u>01/11/17</u>	
Checked by <u>Canita</u> Date <u>02/11/17</u>	
Previous Product Name <u>AAAAA</u> Lot <u>121</u>	
Cleaned Hold Time Date until <u>14/11/17</u>	
Doc No <u>F-011</u> Effective Date <u>12/7/16</u> Rev <u>01</u>	





EQUIPMENT AND UTENSILS

Vacuum or wet cleaning methods are preferred. Compressed air and brushes shall be used with care or avoided if possible, as they increase the risk of product contamination



Compressed air



EQUIPMENT AND UTENSILS

Cleaning agents, washing and cleaning equipment shall not be a source of contamination.

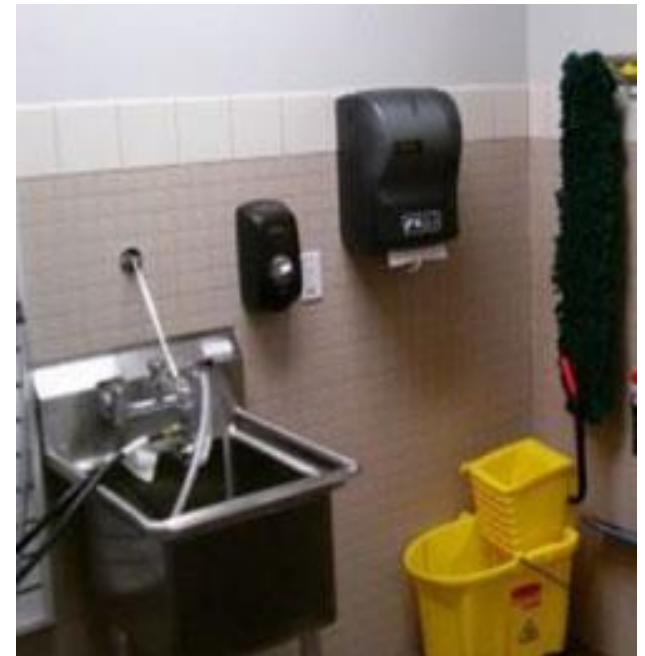
The choice of cleaning method and agents shall be carefully considered and justified.





EQUIPMENT AND UTENSILS

Adequate space, preferably separated from processing areas, shall be provided for cleaning and storing mobile equipment and utensils including the storage of cleaning materials.





EQUIPMENT AND UTENSILS



A separate room may be needed for storing clean, idle equipment which should be kept dry at all times.



EQUIPMENT AND UTENSILS

Written procedures shall be established and followed for cleaning and sanitising of equipment, utensils and containers used in the manufacture of health supplements.

Please see Annex 9 on Cleaning Schedule





EQUIPMENT AND UTENSILS

These procedures shall be prepared to prevent equipment contamination by cleaning or sanitising agents and shall at least include the following:

1. Responsibility for cleaning
2. Cleaning schedule
3. Cleaning methods
4. Equipment and materials used in cleaning operations
5. Methods of disassembling and reassembling equipment
6. Removal of previous batch identification
7. Protection of clean equipment and utensils from contamination prior to use



EQUIPMENT AND UTENSILS

Records of cleaning, including the appropriate sanitising and inspection conducted prior to use shall be maintained.





REFERENCES

1. ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines.
2. ASEAN Guidelines on Good Manufacturing Practice for Health Supplements.

THANK YOU!



ONE VISION, ONE IDENTITY, ONE COMMUNITY