FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

TRAINING MANUAL

Food Safety Supervisor Course Special (Level 3) – Manufacturing

HEALTH SUPPLEMENTS AND NUTRACEUTICALS

FoSTaC

Food Safety Training & Certification

TRAINING MANUAL TO IMPLEMENT GMP/GHP REQUIREMENTS AT HEALTH SUPPLEMENTS AND NUTRACEUTICAL INDUSTRIES

Based on Part II of Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011

Second Edition

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Disclaimer

It is to be noted that this Training Manual does not intend to replace any legal provision of Food Safety & Standard Act, 2006 & regulations there under. Further, wherever the provision of this document conflicts with Part II of Schedule 4 of Food Safety & Standard (Licensing and Registration of Food Businesses) Regulation, 2011 or any other regulation under Food Safety & Standard Act, 2006 for that matter, the provision given in the regulations shall prevail.

PREFACE

Training of food handlers is a pre-requisite for ensuring food safety and the same is also mandated in the FSS Act, 2006. Food Safety and Standards Authority of India (FSSAI) has set up Food Safety Training & Certification (FoSTaC) ecosystem to ensure widespread and effective delivery of training to food business Operators across the value chain. This ecosystem will train and certify the Food Safety Supervisors from each Food Establishment as it is envisaged to make this a regulatory requirement.

This Training Manual on Food Safety Management System (FSMS) is prepared with the intent to provide training to the Food Safety Supervisors (especially the small and medium businesses) involved in manufacturing, packing, storage and transportation of Food Supplements, to ensure that critical food safety related aspects are addressed throughout the supply chain. This manual details the requirements on food safety & hygienic practices to be followed by Food Business Operators engaged in the manufacturing sector. It is based on the Schedule 4 requirements of FSS (Licensing & Regulation of Food Businesses) Regulation, 2011 along with the industry best practices. It has been designed according to the flow of operation in the manufacturing industry for ease of understanding of the Food Safety Supervisors.

This Manual contains practical approaches which a business should adopt to ensure food safety; however, manufacturers may adopt higher or stringent levels, depending on the needs & complexity of operation. The use of this Training Manual is voluntary and food business operators may comply with the requirement of the regulation according to other established best practices.

It is important that food handlers involved in the Food Supplement Supply Chain are trained appropriately to implement the Good Manufacturing Practices and Good Hygiene Practices to ensure food safety.

We acknowledge the contribution of the experts from the ReCHaN (Resource Centre on Health Supplements and Nutraceuticals - A Collaborative initiative of CII and IADSA) team and the technical panel of FSSAI for developing this Manual.

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ACKNOWLEDGEMENT

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WELCOME TO THE MANUAL

The manual is designed for the Health Supplement & Nutraceuticals Industry. This manual explains General Requirements on Hygienic and Sanitary Practices to be followed by all Food Business Operators engaged in the Processing Units, as per Food Safety & Standard Act, 2006. This manual presents bare minimum requirements of Food Safety and Hygiene to be followed by Food Business Operators along with Industry best practices.

LEARNING OUTCOME

The objective of this manual is to train the personal, about food safety and hygiene requirements which are to be followed in their businesses and who can be designated as Food Safety Supervisors in the Health Supplements and Neutraceutical manufacturing and processing Units. The Food Safety Supervisors (FSS) may interpret these requirements according to the size and type of their establishments. The desired outcome of this manual is for better understanding of food safety and hygiene requirements and high standards of food safety practices in the industry.

WHAT THE LAW SAYS

The establishment, where the Health Supplements / Neutraceuticals are processed, packed & handled, by the food business operators, should conform to the sanitary and hygienic requirements, food safety measures and other standards as specified below. It shall also be deemed to be the responsibility of the food business operators to ensure adherence to necessary requirements.

In addition to standards requirements by FSSAI, the food business operators shall identify steps in the activities of Food businesses, which are critical to ensure food safety, and ensure that safety procedures are identified, implemented, maintained and reviewed periodically.

In India, the mandatory sanitary & hygiene requirements for food business operators are – ***"Part II of Schedule 4"***of Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011 **(http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html)** under Food Safety & Standard Act, 2006 **(http://www.fssai.gov.in/home/fss-legislation/food-safety-and-standards-act.html)**.

For the ease of understanding, the relevant sections from Part II of Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 has been segregated as per flow of operations in the Health Supplement Sector.

SECTION A1. OBJECTIVE

The Food Safety Supervisors (FSS) of Health Supplements and Nutraceuticals Industry are to be trained on:

General Requirements on Hygienic and Sanitary Practices, as per *"Part II of Schedule 4"* of Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011

(http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html) under Food Safety & Standard Act, 2006 http://www.fssai.gov.in/home/fss-legislation/food-safety-and-standards-act.html

and Industry Best Practices as applicable to Health Supplements and Nutraceuticals Industry.

Rationale: The GHP GMP and HACCP implementation will help establishments prevent/control physical, chemical, biological hazards resulting from the environment and processes.

SECTION A2. SCOPE

The Food Safety Supervisors shall understand and interpret the food safety and hygiene requirements of GHP, GMP as outlined under Schedule 4, Part II of FSS Act 2006 and Regulations 2011, applicable to the Health Supplement Industry, in accordance with the size and type of their Unit.

SECTION B. IMPLEMENTATION OF GMP, GHP & HACCP

1.0 LOCATION, LAYOUT & FACILITIES

S. No.	Operational Flow	Sub Sec No.	Heading
1.0	Location , Layout & Facilities	1.1	Location and Surroundings
		1.2	Layout and Building design
		1.2.1	General Requirements
		1.2.2	Internal Structures
		1.3	Equipment Design & Installation
		1.3.1	General Requirements
		1.3.2	Hygienic Designing of Equipments
		1.4	Facilities
		1.4.1	Water
		1.4.2	Air Quality and Environment conditions
		1.4.3	Backup & Uninterrupted Power Supply
		1.4.4	Compressed air and other gases
		1.4.5	Lighting
		1.4.6	Hand washing, drying and sanitizing facilities
		1.4.7	Refreshment rooms
		1.4.8	Toilet facilities
		1.4.9	Changing facilities
		1.5	Sector Specific Good Manufacturing Practices

1.0 Location, Layout & Facilities

1.1 LOCATION AND SURROUNDINGS

The manufacturing facility shall be situated away from environmentally polluted areas like open sewage, drain, public lavatory or any factory which produces disagreeable or obnoxious odour, fumes, excessive soot, dust, smoke, chemical or biological emissions to avoid risk of contamination from external environment. In case the above issues are existing, appropriate control measures shall be taken.

The site boundaries shall be clearly identified with appropriate access control to prevent the chances of theft and sabotage.

Dogs, cats or other pet animals should not be allowed to enter the premises.

The manufacturing premise shall not have direct access to any residential area.

The manufacturing premises shall be located away from flood prone area. Where the premises are located in areas prone to flooding, it is recommended that height of the manufacturing area should be suitably elevated to prevent the risks due to flooding.

The surrounding areas of the establishment shall be kept in good order. Roads, yards, parking lots outside the factory building should be free of debris and refuse, and from any source of pollution.

There should not be any stagnant water surrounding the facility. Where buildings are surrounded by grassed or planted areas, clear space and appropriate measures should be taken to prohibit pest harbourage and ingress. Such grassed/planted areas should be regularly tended and maintained.

1.2 LAYOUT & BUILDING DESIGN

1.2.1 General Requirements

The building layout should be designed, constructed and maintained in order to facilitate good manufacturing and hygienic practices.

The building shall provide adequate working space with a logical flow of materials, products, personnel and to the extent that is practicable physical separation of nutrients/ingredients from processed area to prevent any cross-contamination.

Sufficient space and proper placement of equipment's as is necessary for the maintenance of sanitary operations.

The establishment should have a proper space for inward and outward vehicle movement. Openings intending for transfer of materials shall be designed to minimize any cross contamination from foreign matter, pests, etc.

The manufacturer should demonstrate adequate controls (in terms of segregation of area) where there is manufacturing of products like Pre & Probiotics.

Designed, constructed and maintained to prevent entry of insects and rodents.

1.2.2 Internal Structures

1.2.2.1 Walls, Ceilings and Partitions

Walls, Ceilings and Partitions shall be soundly constructed of materials that are durable, cleanable, impervious to food, grease and water with no toxic effect in intended use. For example: emulsion oil paint (which is easily cleanable by wiping); tiles (which are less porous and causes less crevices), are to be used.
The premises shall be free of flaking paint and plaster to prevent the accumulation of dust, minimise dirt & condensation, growth of moulds and shredding of particles.

Wall floor joints should be curved/coved in processing and packaging areas to facilitate cleaning. Walls & Floors should not be damp or moist.

Walls and pillar guards (SS) should be used to avoid daily wear and tear of the surfaces.

Walls & Ceiling joints must be sealed to prevent the entry of dirt, dust and pests.

1.2.2.2 Overhead fixtures

Shall be suitably protected so that they do not act as contaminants in case of breakage.

1.2.2.3 Floors:

Floors shall be non-slippery, sloped appropriately, to allow adequate drainage and shall be made of materials that are durable and easy to clean such as Epoxy coated floors or PU flooring or any other suitable flooring. Wet cleaning, which makes the floor slippery, should be avoided.

Wall and floor joints should be made as curved so that it is easily cleanable. The Floors shall be damp free, maintained in good repair with no cracks and crevices, easy to clean and disinfect. Sweeping and mopping are to be appropriately done.

Smooth Floors with appropriate slope and drainage facility

1.2.2.4 Drains

Drains should be covered to prevent insects and rodents from entering the packaging, storage, ingredients/nutrients and processing areas. The drainage shall flow in a direction opposite to the direction of food preparation area.

All openings such as manholes, inlets, outlets, draining out points should be effectively locked / sealed.

Covered Drains to prevent entry of pests

Floor with proper drainage facility

1.2.2.5 Doors, Windows, Roof Vents, Exhaust Fans

Doors & windows shall be made of smooth, non-absorbent surfaces, easy to clean and disinfect.

Shall be fitted with automatic closing springs, well screened with wire-mesh or insect-proof screen to protect the premises from pests.

Gaps in between the door and the floor should be closed with suitable material like rubber strips, polyurethane etc. to avoid pest entry.

Entry / exit points should be suitably protected with strip PVC/air curtains/ doors with automatic self-closing devices, to ensure protection from dust, insects, birds and animals.

External opening windows, roof vents or exhaust fans, shall be adequately screened to avoid any external pest ingress.

Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes should be situated / constructed and well maintained as not to cause contamination to ingredients/ nutrients, packaging materials and finished goods.

Doors made of smooth and non-absorbent surfaces

Well screened windows

1.3 EQUIPMENT DESIGN & INSTALLATION

1.3.1 General Requirements

Equipments and containers that come in direct contact with food and are used for food handling, storage, processing, packing, shall be

- specifically labelled, identifiable & stored separately.
- suitably designed and fabricated so that it permits necessary maintenance and periodic cleaning, kept in good order, repair and condition, i.e. free from cracks, crevices, open seams etc. as to minimize risk of contamination.
- made of impervious, corrosion free material which do not impart any toxicity to the food material and shall be easy to clean.

- made of Food Grade Material (reference FSSAI food contact material standards), posing no threat to the product.
- placed to achieve easy and effective cleaning of adjacent areas like floors, walls, ceilings and other surfaces.
- provided with a properly fitted cover or with a clean gauze net or other material of texture sufficiently fine to protect the ingredients/nutrients/work in process/finished goods completely from dust, dirt and flies and other insects.
- Kept away from obnoxious fumes and gases to avoid contamination.

1.3.2 Hygienic Designing of Equipments

Hygienic designing of Manufacturing vessels, pipes and material handling equipment's to have :

- well bonded and smooth material in use, to promote sanitary conditions.
- sloped pipes, with no dead-legs or right-angled bends,
- domed tops, curved sides, conical bases for vessels/tanks.
- flexible hoses with smooth (not ribbed) internal surface for easy cleaning with sanitary fittings which are easy to connect /disconnect hoppers.

Adequate control measures and appropriate facilities to be made available for cleaning, disinfecting, sanitizing to ensure avoidance of cross-contamination. Clean-In-Place (CIP) should be adopted, wherever possible.

Defective equipment shall be removed from production and quality control areas. If any equipment cannot be removed, they should be clearly indicated with their status.

Hygienically designed Equipments made of SS

Cleaning of Equipments

1.4 FACILITIES

The facilities are essential utilities / services that play a vital role to industry. Quality facilities and utilities like air, water, light, hygiene facilities etc, are to be provided and are a prerequisite for effective implementation of food safety and hygiene practices in an Organization. Back-up systems and other parallel infrastructure systems can be planned for continuous & uninterrupted supply.

As Industry Best Practices Qualification of the Utilities (Water Systems, HVAC, Compressed Air/ Gas others) should be done to give a confidence of reliable, continuous & uninterrupted supply of desired quality.

Pipe-work, electrical fittings, ventilation openings and similar services lines shall be designed, fixed and constructed to avoid creation of recesses. Service lines shall be identified, marked by colours and the nature of the supply and direction of flow shall be indicated.

The facilities that play vital role in a Health Supplement & Nutraceutical industry are :

1.4.1 Water

1.4.2 Air Quality and Environment conditions

1.4.3 Power Backup & Uninterrupted Power Supply

1.4.4 Compressed air and other gases

1.4.5 Lighting

1.4.6 Hand washing, drying and sanitizing facilities

1.4.7 Toilet facilities

1.4.8 Changing facilities

1.4.9 Rest and Refreshment rooms

1.4.1 Water

Adequate supply of potable water shall be available to meet operational needs. For steam / Ice as a product ingredient, potable water to be used.

For equipment and plant cleaning or in contact with food or food contact surfaces, potable water shall be used.

Potable water used as an ingredient shall be analysed at least semi-annually to confirm that it meets the requirements of IS 10500 Standard.

Storage tanks and water pipes shall be adequately designed, made of material that is non-toxic, corrosion resistant material and periodically cleaned and maintained to prevent contamination and records of the same should be maintained. The tanks shall be covered to prevent access and cross contamination from animals, birds, pests and other extraneous matter.

Water filters shall be regularly monitored and effectively maintained.

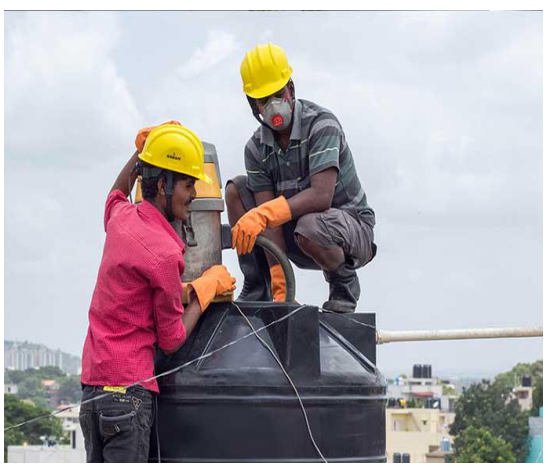
Recycled water used in processing or as an ingredient shall be potable and not present any risk of contamination.

The material used for construction of pumps, valves, storage and distribution lines shall be non-reactive, non-corrosive, non-leaching and sanitary in design.

Water lines for supply of portable water (used in internal Cleaning & as ingredients) shall be clearly separated and identified from others. Colour coding of separate pipelines for potable water and non-potable water is recommended.

Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems. Non potable water can be used for cleaning of equipment not coming in contact with Food, refrigeration equipment, Fire Fighting.

Multiple Water lines and CIP System



Cleaning of water storage tanks

Colour coding of water pipes

Demarcation of pipelines

1.4.2 Air Quality, Environment conditions & Ventilations

Air quality and environment conditions recommended for various areas are as follows:

- For Material sampling / Dispensing/ Product Contact Area/ Process Equipment Storage Area – ISO 8 with RLAF ISO 5, temperature should not be more than 25° C and Relative Humidity (RH) should not be more than 60%+/- 5%. For certain products a lower and more stringent RH and temperature control may be required.
- For Process Equipment Washing Area – the negative pressure should be with respect to the Processing Area.
- Input Material Storage Area – environment conditions as per requirement.
- Finished Product Storage Area – as per the established stability studies.
- Microbiological / Analytical Laboratory – ISO 8 with LAF ISO 5, (Dedicated AHU to be provided for Microbiological Lab); temperature should not be more than 25° C and Relative Humidity (RH) , should not be more than 60%+/- 5% . Certain products may require a lower and more stringent RH and temperature control.

Adequate gradation of the surrounding area shall be designed to maintain the integrity of the targeted class.

The air shall not flow from contaminated to clean areas, the ventilation systems shall be so designed.

Adequate Differential Pressure shall be maintained between different classified areas. Recommended differential pressure in adjacent areas should be min 0.5 mm of Water Column (5-10 psi).

Air filters, exhaust and air intake ports shall be examined periodically for physical filter integrity. Periodic air quality monitoring shall be in place (e.g. Total Plate Count or as is applicable to the specific industry).

Ventilation systems, natural and/or mechanical, including Heating, Ventilation and Air Conditioning (HVAC) systems or air-conditioning, air filters, exhaust fans, wherever required, shall be designed and constructed so that air does not flow from contaminated areas to clean areas. Systems shall be accessible for cleaning, filter changing and maintenance.

1.4.3 Power Backup & Uninterrupted Power Supply

Uninterrupted power supply should be ensured through appropriate means to facilitate smooth processing/production.

1.4.4 Compressed Air and other Gases

Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.

Compressed air / gases intended for direct or incidental product contact shall be from a source approved for food contact use, filtered to remove dust, oil and moisture to ensure microbial quality and shall be checked at least once in a year. In case of any changes in the system a retest has to be done before starting the production.

Use of Oil free Compressed air system only is recommended.

1.4.5 Lighting

Adequate natural or artificial lighting shall be provided to enable the personnel to operate in a hygienic manner. The lux level of lights should be adequate to the nature of the operation.

The lighting system should not result in misleading of colour.

Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in case of breakages.

Sufficient lighting facility in the Work Area

All Lights are to be covered

1.4.6 Hand washing, Drying and Sanitizing facilities

Hand washing facility with mixing taps of Hot and Cold Water with suitable hygienic means of drying hands shall be made available ***at the entrance of the Processing areas***.

Hand washing notices and procedure shall be posted on walls near hand wash stations.

Non- Perfumed liquid soap should be used in dispensers to wash hands as soap bars are a potential source of cross contamination.

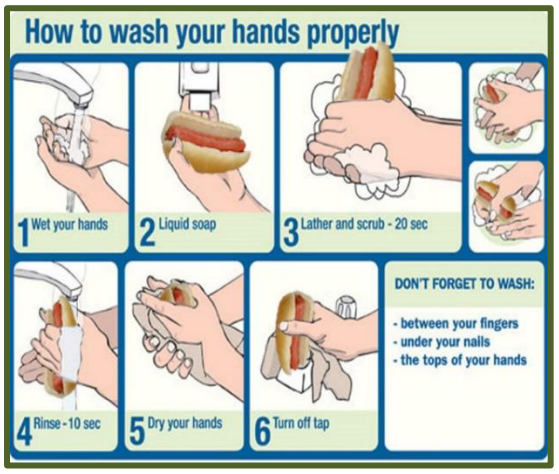
Elbow or foot operated taps should be used such that there is no hand contact after washing while closing the taps.

Hand driers where installed should be in working condition at all the times during working hours.

Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Paper towel rolls should be covered from top at all time to avoid dust and dirt on them.

The dustbins used to throw the used-paper towels, should be foot-operated to avoid any direct hand contact (washed hands) to open the dustbin.

Self-drying hand sanitizer should be provided after drying of hands, which helps in disinfecting hands after cleaning (e.g. a good practice is IPA 70% for hand sanitisation).



1.4.7 Toilet Facilities

Toilets shall be separate from other areas and shall not be directly connected to the storage and manufacturing/processing areas. Separate and sufficient number of toilets

/urinals with adequate supply of water, separate for male and female should be provided. Industry best practice of 1:25 is followed for facility: employee ratio.

Potable water should be used at the hand wash stations.

All toilet facilities should be clean and sanitized at all times of the working hours. Toilets should be so designed so as to ensure hygienic removal of waste matter. Toilets should be well lit and ventilated and should not open directly into food handling areas.

1.4.8 Changing Facilities

Suitable and sufficient facilities for persons working in the processing areas should be provided for changing their clothes, keeping their personal belongings and Street footwear before access to the processing area.

- Separate shelf / storage space should be provided for personal clothes and company uniforms.
- Factory Footwear should be cleaned periodically and not to be used for external purposes.
- Personal Belongings should be kept in Lockers.

Separate lockers for men and women for changing of clothes

1.4.9 Rest and Refreshment rooms

Rest & Refreshment Rooms shall not lead directly to the manufacturing and storage areas and shall be separated from other areas.

Staff canteens shall be available to ensure hygienic storage of prepared food. Employees' shall consume their food in Refreshment Rooms only, away from Process & Storage area.

Display board mentioning "Dos" and "Don'ts" for workers should be posted in a prominent place inside the premises, in English/local language, for all to understand. This will help all the employees to maintain their alertness on Good Hygiene Practices.

Food shall be consumed in Refreshment Room and not in Rest Room

1.5 SECTOR SPECIFIC GOOD MANUFACTURING PRACTICES

Movement of material and methods should not be from low to high risk area.

High risk area: The area where product/material is exposed, having controlled temperature, humidity and differential pressure, i.e. the processing, primary processing, filling, sampling, dispensing areas. High risk zone should be monitored for environmental conditions in respect to microbial loads.

Low risk area: The area where product/ material is not exposed like, Washing, Secondary Packing area, Warehouse.

2. MATERIAL HANDLING

Section No.	Operational Area	Sub-Section No.	Topics
2.1	Receiving	2.1.1	Control Operations – Supplier Approval & Procurement of Raw Materials
		2.1.2	Origin of Botanicals
		2.1.3	Botanicals identification & Characterization
2.2	**Storing**	2.2.1	Storage and Material Control
		2.2.2	GHP of Storage Area

2.0 Material Handling

2.1 RECEIVING

2.1.1 Control Operations – Supplier Approval & Procurement of Ingredients/ Nutrients and Packaging Materials

Supplier Quality Development Programme laying down the criteria for selection, approval, review and ongoing approval should be implemented.

All raw materials, process aids, ingredients, packaging material or any other material lots shall be procured from internally approved suppliers who are FSSAI/FDA/ AYUSH licensed/ registered or licensed from other regulatory authorities. An approved supplier should be evaluated as per the quality supplied and other relevant factors.

Ingredients/nutrients received shall be according to the storage and processing capacity of the processing plant. All ingredients/nutrients and packing material and process aids, shall conform to all Standards laid down under the relevant regulations, inspected and sorted before processing.

Procedures in place shall be available to confirm that the incoming materials meet the documented specifications through certificate of analysis, visual inspection, laboratory testing, review of label for allergens etc. It is recommended to have food grade certificates for applicable food processing aids, packaging and other food contact material from suppliers.

Records of ingredients/nutrients or any other material used in processing as well their source of procurements shall be maintained for traceability.

All bulk tankers/ containers shall be checked for seal integrity, cleanliness and others as per the inspection checklist at the time of receipt.

All packaged ingredients/nutrients shall be checked for ‘expiry date’/’best before’/’use by date’, packaging integrity and storage conditions.

The incoming vehicles that bring the raw materials, shall be checked for cleanliness and hygiene i.e. the trucks are clean, with no pests or dirt, with no strong odour other than that of the raw material.

2.1.2 Origin of Botanicals

The name and origin of botanical should be ascertained. The botanical shall be traceable by a Batch no. / Shipment ID.

Written confirmation to be made available for the relevant batches / lots to show that cultivation / collection, harvest, storage and processing were in compliance with the basic principles of Good Agricultural and Collection Practices, in relation to identification and traceability.

2.1.3 Botanical identification & Characterization

The plant part used in the botanical preparation shall be ascertained like

- Whole plant / Underground parts / Specific Roots / Rhizome / Tuber / Bulb
- Aerial parts of the plant / Stem Specific / Bark / Leaves / Flower / Fruit / Seed

The Identification of the unprocessed botanical shall be confirmed by any of the following methods: − Microscopic or Macroscopic examination,

− Chromatographic or Spectroscopic examination
− Other characteristic assay
− Physical tests

The traceability records should be available from point of plant growth (not mandatory).

2.2 STORING

2.2.1 Storage & Material Control

Storage areas and vehicles at loading & unloading bays shall be designed, constructed, adapted and maintained to facilitate the operations carried out in them and to prevent damage to the stored materials.

Ingredients/Nutrients, packing material and finished goods shall be stored in clean, dry, well ventilated spaces protected from dust, odours condensation, fumes or other sources of contamination.

Materials and product shall be suitably stacked with due regard given to food safety. Aisles should be kept clear and not used for temporary storage of materials.

Receiving and dispatch bays shall be provided for receiving of material and dispatching of finished products from the storage areas, shall be designed to protect materials and products from the weather.

Receiving areas shall be equipped to allow containers of incoming materials to be cleaned where necessary.

Adequate spacing should be maintained between pallets to ensure sufficient ventilation. Periodic visual checks should be made of all pallets, racks and other storage infrastructure, w.r.t structural integrity and infestations.

There should be a separate sampling & dispensing area in the warehouse.

Ingredients/Nutrients shall be stored as per the storage conditions mentioned on the label or as specified by the vendor. Storage area temperatures and RH shall be monitored at stipulated frequency.

All materials and product should be clearly marked with their relevant Identification/Lot Number, to maintain the traceability. The identification marking should be easily accessible/visible even when the material or product is stacked.

In case Fresh material of botanical origin is used as a raw material, it shall be stored in a separate dedicated area with appropriate controls.

Printed packaging materials shall be stored in dry, dust free, safe, separate and secured manner.

Storage Tanks

Storage Containers

2.2.2 GHP of Storage Area

Cleaning of Storage Areas: Storage premises and equipment's must be effectively cleaned at defined frequency. Storage areas should be regularly inspected for cleanliness and good housekeeping. Cleaning standard operating procedures (SOPs) shall be defined and records demonstrating compliance shall be maintained.

Materials and methods used for cleaning are specified in well-designed cleaning schedules and procedures. Receipt of cleaning materials should be accompanied with Material Safety Data Sheet (MSDS) documents and stored in a separate and secured location in order to avoid contaminations.

Damaged, Rejected & Recalled Goods: Damaged goods should be placed in a designated place physically segregated from Good stocks and properly labelled.

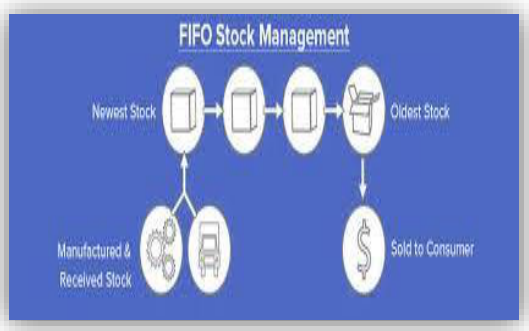
Products which have been recalled or returned, and lots which have been rejected for re-working or recovery of materials or disposal should be so marked and physically segregated and identified.

Only products which have been properly inspected to ensure that the product and packaging are fully acceptable may be re-packed into outer packaging in a suitable area.

If it is necessary to re-pack goods of different production codes into the same outer-packaging, the package should be marked with a date of minimum durability (Best Before date).

Records for such returned or recalled materials shall be properly maintained, as per the FSSR recall regulation 2017.

Stock Management



Access Control: Access to material and product storage areas should be restricted to those working in those areas and to other authorised persons only.

Suitable air curtain should be provided at all entrances and exits opening to the external environment, in order to maintain the internal conditions of the storage area at an appropriate level for the product therein.

When the storage area is connected directly to the manufacturing area, a buffer area/pass box/ air lock should be provided between the storage area and the manufacturing area.

Access to High Risk Zone can be controlled through Biometrics.

3.0 PRE -PRODUCTION PROCESSING OF HEALTH SUPPLEMENTS & NUTRACEUTICALS

Section No.	Topics
3.1	General Requirements - Operations & Control of Health Supplements & Nutraceutical Processing / Preparation
3.2	Botanical Extract Preparation

3.0 Pre -Production Processing of Health Supplements & Nutraceuticals

3.1 GENERAL REQUIREMENTS -

Operations & Control of Health Supplement & Nutraceutical Processing / Preparation

Flow diagrams, Standard Operating Procedures of processing operations shall be documented, implemented and displayed at Operations site.

Standard operating procedures for process changeover from one kind of product to another shall be maintained and implemented.

Records shall be maintained for critical parameters like temperature / vacuum etc., for daily process with appropriate coding for traceability.

Intermediate in-process samples taken and tested for critical parameters and test results records shall be maintained.

Cleaning schedule for equipment in the food processing sections shall be maintained.

Systems should be in place to prevent contamination of foods by foreign bodies such as glass, metal pieces from machinery and dust.

During processing operation, suitable detection or screening devices shall be used where necessary.

Access to High Risk Processing Areas shall be only via a changing facility.

For presence of identified allergens in ingredients and finished products, controls shall be put in place to prevent their presence in foods.

All manufacturing operations shall be carried out under the supervision of authorised technical persons.

Each critical step in the process relating to the selection, weighing and measuring of raw material, shall be performed by trained personnel under the direct personal supervision of authorised technical person.

Adequate space away from processing areas, shall be provided for cleaning and storing of mobile equipment’s, containers and cleaning materials.

Incoming materials and finished products shall be placed in designated areas immediately after receipt, until released for use or distribution. Intermediate and bulk products purchased shall be handled on receipt.

Operations on different products shall not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or cross-contamination.

The contents of all vessels and containers used in manufacture and storage during the various manufacturing stages shall be conspicuously labelled with the name of the product, batch number, batch size and stage of manufacture. Each label should be initialled and dated by the authorised technical staff.

3.2 BOTANICAL EXTRACT PREPARATION

Preparation derived from botanical extracts shall be identified as Extracts, Comminuted, Powdered herbal substance; Essential oil; Expressed juice; Processed exudate and others. Form of Botanical Extracts are to be identified as standardized extracts / quantified extracts / other extracts. The Markers present in the botanical extract/other preparation shall be identified as Active markers/ Analytical markers.

When Standards of Botanicals are not specified, the purity criteria generally accepted by pharmacopoeias, are either /or:

- Indian Pharmacopoeia,
- Ayurvedic Pharmacopoeia of India,
- Specifications of Bureau of Indian Standards ,
- Quality Standards of Indian Medicinal Plants,
- Indian Council of Medical Research,
- British Pharmacopoeia,
- United States Pharmacopoeia,
- Food Chemical Codex,
- Joint Food and Agriculture Organization
- World Health Organization
- Expert Committee on Food Additives
- CODEX Alimentarius may be adopted by food Business operators.

Botanical Extract Preparations

4.0 PRODUCTION OF HEALTH SUPPLEMENTS & NUTRACEUTICALS

Section No.	Topics
4.1	Manufacturing Requirements for Tablets & Capsules
4.1.1	Manufacture of dosage forms (tablets and capsules)
4.1.2	Sifting, Mixing, Blending and Granulation
4.1.3	Compression of Tablets
4.1.4	Coating of Tablets
4.1.5	Encapsulation - Capsules (Powder & Liquid Filled)
4.1.6	Printing (Tablets and Capsules)
4.1.7	Packaging of Tablets & Capsules
4.2	Manufacturing Requirements for Liquids
4.2.1	**Building and Equipment**
4.2.2	**Water Treatment**
4.2.3	Manufacturing Process for Liquids
4.3	Manufacturing of Powders
4.4	Allergen Management
4.4.1	Allergen Handling
4.4.2	Allergen Control and Management
4.5	Packaging & Warehousing
4.5.1	Packing
4.5.2	Warehousing
4.6	Rework & Control of Non – Conforming Products

4.0 Production of Health Supplements & Nutraceuticals

4.1 MANUFACTURING REQUIREMENTS FOR TABLETS & CAPSULES

4.1.1 Manufacture of dosage forms (tablets and capsules)

Dust Control systems shall be employed while processing of dry materials to avoid any cross contamination.

A process of Line clearance shall be implemented before various processes like dispensing, mixing, sieving, blending, compression, packing.

All raw materials and ingredients shall be tested and released prior to dispensing as per BOM (Bill of Material). All ingredients for dry product shall be sifted before use. All materials shall be protected from metal, wood, plastics and other foreign particles.

Air conditioning shall be provided to avoid any cross contamination during processing.

There should be no evidence of lubricants leaking into the product from any part of the equipment. As a good manufacturing practice food grade lubricants should be used where possibility of incidental contact exists. Air-extraction nozzles of compressed air are to be kept clean. Air entering the driers shall be filtered. Filters shall be installed in air extraction systems with discharge points to retain dust and protect the factory and local environment.

Screens, sieves, punches and dies shall be examined for wear and tear or for breakage before and after each use.

Pressure differentials between rooms shall be regularly monitored and any deviation shall be brought to the immediate attention of the Production and Quality Assurance Department. The maximum period of storage of the bulk materials shall be validated and specified.

4.1.2 Sifting, Mixing, Blending and Granulation

The Integrity of sieves before and after the process has to be ensured. Residues from sieving operations shall be examined periodically for evidence of the presence of unwanted materials. Sieves and screens in the sieving equipment’s should be free from lead.

Filter bags fitted to fluid-bed drier shall not be used for different products, without being washed in-between use.

With certain highly potent or sensitizing products, bags specific to one product only shall be used.

Blending time and RPM shall be recorded in the manufacturing record. Sifting and blending equipment’s shall be fitted with dust extractors or air handling unit for control of dust.

Mixing time, temperature and ampere load and other key parameters shall be recorded in the batch manufacturing record.

Sifting, Mixing, Blending & Granulation Compression Stations with individual Cubicles

4.1.3 Compression of Tablets

Tablets from each compression station are to be inspected at fixed intervals for pharmacopeia parameters like appearance, weight variation, disintegration, hardness, friability, thickness and contamination by lubricating oil. The results shall be recorded in the batch manufacturing record. Each Compression machine shall be installed in separate cubicles, within its own enclosed air controlled environment. Tablets shall be collected into clean, labelled containers. Tablets shall be de-dusted and monitored for the presence of foreign materials besides any other defects.

Weighing equipment's shall be calibrated for in-process monitoring of tablet weight variation.

Labelling shall be done of all the in-process material, granules and tablets to prevent any mix up during compression process.

In-process control shall be employed to ensure that the products remain within specification. Procedures shall be in place for detecting out-of-limit tablets. Rejected or discarded tablets shall be isolated in identified containers and their quality recorded in the Batch Manufacturing Record.

Compression of Tablets

Coating of Tablets

4.1.4 Coating of Tablets

The preparation and use of coating solution shall be documented and recorded. The Coating solution shall be freshly made to minimize the risk of microbial growth.

Air supplied to coating pans for drying purposes shall be filtered air and of suitable quality. The area shall be provided with suitable exhaust system and environmental control (temperature, humidity) measures.

4.1.5 Encapsulation - Capsules (Powder & Liquid Filled)

Capsules shall be stored under adequate environmental conditions ensuring safety from the effects of excessive heat and moisture.

Industry best practices for environment conditions of this area are Temperature not more than 25 Degrees Celsius and RH not more than 60 +/- 5%or as per the product requirements.

Encapsulation

4.1.6 Printing (Tablets and Capsules)

Tablets and capsules after printing shall only be released after approval from quality control.

Edible grade colours and suitable printing ink shall be used for such printing.

Special care shall be taken to avoid product mix-up during any printing of tablets and capsules.

Where different products, or different batches of the same product, are printed simultaneously, the operations shall adequately be segregated.

4.1.7 Packaging of Tablets & Capsules

Prior to commencement of any operation, an independent check of the packaging equipment is to be maintained. Packaging material shall be tested against laid down standards and released prior to dispensing.

Line clearance shall be done before dispensing of packing material and before a new packing operation starts. It is to be ensured that all tablets, capsules or foils of the previous batch are removed before a new packing operation starts.

Integrity of individual package shall be subjected to vacuum test or other suitable methodology, periodically to ensure leak proof seal integrity and records shall be maintained.

Uncoated tablets shall be packed on equipment designed to minimize the risk of cross-contamination. Such packing shall be carried out in an isolated area.

The package coming out of the machine shall be inspected for defects such as misprint, No-fill, cuts on the foil, missing tablets and improper sealing.

Outdated or obsolete primary packaging material or printed packaging material shall be destroyed and recorded.

As Industry Best Practices, in-case tablets or capsules in the pack can't be seen or counted after primary packing, the Primary packaging machines for packaging of Tablets or Capsules should have No fill detectors, metal detectors and check wares to check for empty packets, metal contamination and broken tablets.

Packing of Tablets

Packaging Machine for Tablets & Capsules

4.2 MANUFACTURING REQUIREMENTS FOR LIQUIDS

4.2.1 Building and Equipment

The premises and equipment shall be designed, constructed and maintained to suit the manufacturing of Liquids. Entry to the manufacturing area shall be through a double door airlock facility. Fly catcher and/or air curtain can be used to make it fly proof.

Cleaning and sanitation shall be done of the manufacturing area after every production batch. Containers and droppers shall be cleaned with high pressure air, water and steam jets.

Equipment design shall be such as to prevent accumulation of residual microbial growth or cross-contamination.

Stainless steel or any other appropriate food grade material shall be used for parts of equipment's coming in direct contact with the products.

Tanks, containers, pipe work and pumps shall be designed and installed so that they can be easily cleaned and sanitized.

The furniture used shall be smooth, washable and made of stainless steel or any other appropriate food grade material.

Machineries use for Manufacturing of Liquid Health Supplements

4.2.2 Water Treatment

The operation system of Water treatment and maintenance shall be defined. Methods like re-circulation, use of UV, heat and chemical sanitation can be used to minimize the risk of microbial contamination.

Flushing shall be done after every chemical sanitation. Water shall be demineralized (free from minerals) & should qualify Indian Pharmacopeia IP 14.

The water quality shall be monitored periodically for chemical and microbiological contaminants.

4.2.3 Manufacturing Process for Liquids

Manufacturing personnel shall wear non-fibre shedding clothing to prevent contamination of the product. Mixing and filling processes shall be specified and monitored.

Care shall be taken at the beginning of the filling process, after stoppage due to any interruption and at the end of the process to ensure that the product is uniformly homogenous during the filling process. The maximum period of storage conditions of the liquid shall be specified in the Master Formula.

The maximum period of storage time of a product in the bulk stage shall be validated. The homogeneity of emulsion shall be maintained by use of appropriate emulsifier and suspensions by using appropriate stirrer during filling.

The primary packaging area shall have an air supply which shall be adequately filtered.

4.3 MANUFACTURING OF POWDER

The environment conditions of the manufacturing area shall be controlled. Air shall be adequately filtered and conditioned. Recommended air quality in the processing area is ISO 14644-1/2:2015.

The entrance to the production area shall be through a suitable airlock. Outside the airlock, Insectocutors shall be installed.

The area shall be fitted with an exhaust system of suitable capacity to effectively remove vapours, fumes, smoke, floating dust particles.

The equipment used shall be designed and maintained to prevent the product from being accidentally contaminated with any foreign matter or lubricant.

Primary packing should be done in a separate section. No rags or dusters shall be used in the process of cleaning or drying the process equipment or accessories in use.

Water used in compounding shall be potable water. Powders shall be suitably sieved before use.

4.4 ALLERGEN MANAGEMENT

4.4.1. Allergen Handling:

Major Allergens are –

1) Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products;
2) Crustacean and products made out of it ;
3) Eggs and egg products;
4) Fish and fish products;
5) Soybeans and products made out of it;
6) Milk and milk products;
7) Peanut, tree nuts and nut products; and
8) Sulphite in concentrations of 10 mg/kg or more.

Cereals containing gluten

Tree nuts and nut products

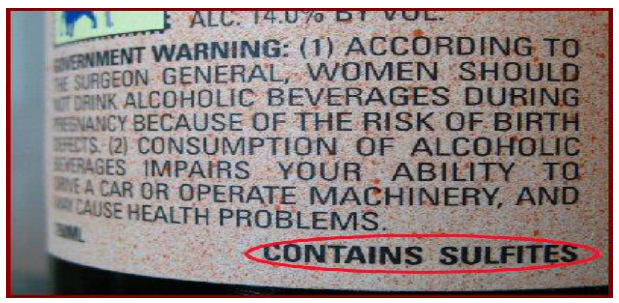
Milk and milk products

Crustacea and its products

Eggs and Egg Products

Fish and fish products

Peanuts, soybeans and their products



Sulphite in concentrations of 10 mg/kg or more

4.4.2. Allergen Control and Management

All allergens are to be displayed at the relevant places in the processing and storage areas and trainings are to be conducted for awareness among all the employees. All raw materials that are allergens should be labelled with a tag that states “Allergen.”

During manufacturing, ingredient flow from non-allergen using areas to allergen using areas to be maintained to help prevent cross-contamination. Products containing non-allergen ingredients should run before the product containing allergic ingredients.

All allergic foods or ingredients are to be stored at a designated area. For partially used allergic packets, the production staff should ensure the partially used packet should be stored separately and completely sealed and identified with labels.

Dedicated scoops, utensils shall be used for specific allergens. Thorough cleaning practice should be there between allergic containing product manufacture and non-allergic containing product manufacture.

4.5 PACKAGING & WAREHOUSING

4.5.1 Packaging

The packaging materials used shall be robust and secure enough to provide protection, prevent spoilage and contamination during transit to all Health supplements / Nutraceuticals products packed within. Required labelling as laid down under the FSS Act & the Regulations to be followed.

Food grade packaging materials shall be used for packing all Health Supplements / Nutraceuticals coming in direct contact. Packaging materials like aluminium, tin and plastic shall conform to BIS standards as mentioned under the FSS Regulations. The packaging materials or gases where used, shall be non-toxic and pose no threat to the safety and suitability of food under the specified conditions of storage and use.

Packaging section shall always be considered as a high risk zone and access to packaging section shall be restricted and controlled via changing facility.

Personnel shall put on clean protective clothing and footwear before entry.

Packaging materials for Health supplements / Nutraceuticals shall be inspected before use to prevent using damaged, defective or contaminated packaging, which may lead to contamination of the product.

The food business operator shall have effective procedures in place to confirm that contaminated, damaged or defective reusable containers are properly cleaned and sanitized, repaired or replaced, as appropriate, before re-use.

All packaging equipment like weighing scale shall be calibrated on daily basis against certified standards of National and/or International standards & their records are to be maintained.

Filling and packaging shall be done under hygienic environment in a separate designated area that are closed from all sides to restrict entry of flies, rodents, birds and pests. Normally, filling and sealing shall be followed as quickly as possible by labelling. Appropriate procedure shall be applied to ensure that no mix-ups or mislabelling occur.

Packaging of Health Supplements

4.5.2 Warehousing

All packed goods shall be stored at least 18 inch away from walls and on pallets or raised platforms (like racks, cupboards) and not stored directly on floor.

The warehouses shall be kept clean, dry, ventilated and under hygienic condition to avoid pest infestation, dirt, dust, smell.

Where specified for a particular Health Supplement/ Nutraceuticals, temperature and humidity control systems shall be introduced and carried out with calibrated recording equipment with appropriate maintenance of records.

Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State Legislations.

Warehousing and Distribution Facility

4.6 REWORK & CONTROL OF NON – CONFORMING PRODUCTS

A non-conforming product can be detected through incoming material inspection, during normal testing and inspection activities, internal defect findings, internal audits, external audits, incoming material inspection and or through customer complaints.

All rework/non-conforming/market returned materials shall be segregated, identified, stored, handled, labelled and used in such a way that product safety, quality, traceability and regulatory compliance are maintained. All Traceability records for rework shall be maintained.

Stored rework/non-conforming/market returned material shall be protected from exposure to microbiological, chemical or extraneous matter contamination.

Where rework/non-conforming/market returned is incorporated into a product as an “in-process” step, the acceptable quantity, the process step and method of addition, including any necessary pre-processing stages, shall be pre-defined.

Where ever rework activities involves removal of product from filled packages adequate controls shall be put in place to ensure removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

Standard operating procedure should be defined and documented for handling any rework or non-confirming products.

Additional inspection of reworked/reprocessed in-process or finished product is to be documented.

5. TRANSPORT, HANDLING & DISTRIBUTION OF HEALTH SUPPLEMENTS & NUTRACEUTICALS

5.0	Transportation, Handling & Distribution

5. Transport, Handling & Distribution of Health Supplements & Nutraceuticals

Adequate transportation facilities shall be in place, designed and constructed to permit adequate cleaning and/or disinfection.

Conveyances and/or containers used for transporting Health supplements/ Nutraceuticals shall be kept clean and maintained in good repair to protect from contamination.

The vehicle interior (including walls, floor and ceiling) should be inspected for general cleanliness, freedom from moisture, foreign materials, damage, insect or rodent infestations, objectionable odours or other forms of contamination.

A procedure should be established to deal with damage occurring when goods are in storage or distribution.

Security precautions shall be established for deterring and preventing any tampering with goods in storage and distribution.

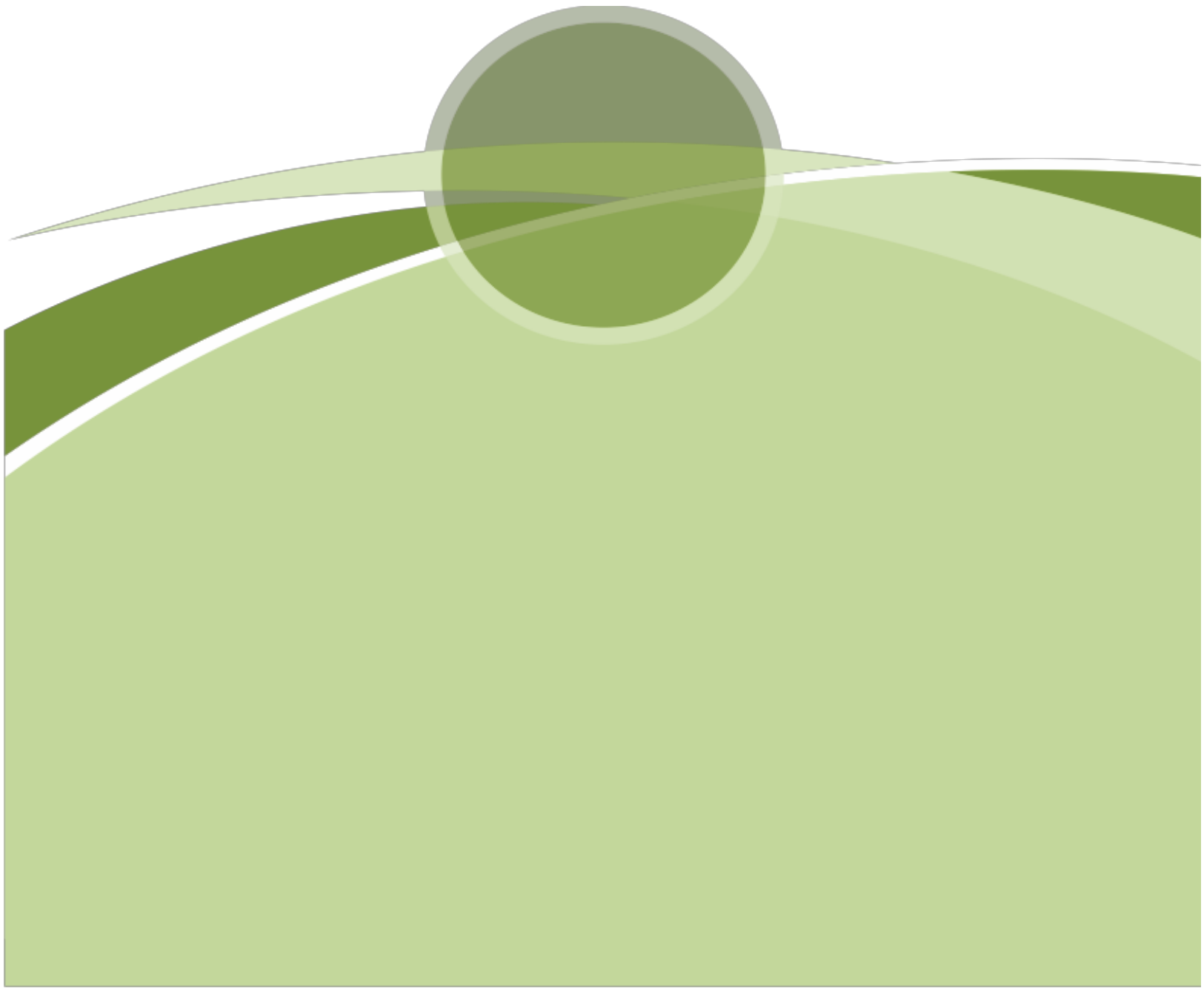
Any docks, railway sidings, bays, driveways, etc. within the factory complex should be kept free from accumulation of debris and spillage.

Fork lift and other trucks used within the storage areas should normally be battery driven or otherwise equipped to prevent fume or fuel contamination.

Dispatches of finished goods must follow FIFO or FEFO (First Expiry First Out) system.

6.0 PERSONAL HYGIENE

Section No.	Topics
6.1	Health Status , Illness & Injury
6.2	Behavior & Personal Cleanliness
6.3	Personal Behavior
6.4	Protective Clothing
6.5	Visitors Control



6.0 Personal Hygiene

6.1 HEALTH STATUS, ILLNESS & INJURY

Health supplement/ Nutraceutical handlers of the manufacturing facility shall undergo a medical examination by a registered medical practitioner before joining for work and thereafter annually to ensure that they are free from any infections and other communicable diseases. A record of these examinations shall be maintained.

The employees in the manufacturing premises shall be inoculated against the enteric group of diseases as per recommended schedule of the vaccine and a record shall be maintained.

Personnel known, or, suspected to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food shall be prevented from handling material or products which come in contact with the finished goods.

After illness or injury nobody can return to work without “Fit to Join” Certificate from a Medical Practitioner. System of Self – medication by the Handlers / employees should be controlled.

Food handlers shall report the following conditions to the management for possible exclusion from food handling areas – jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected lesions, (boils, cuts or sores) and discharges from ear, eye or nose.

Medical examination of a food handler shall be carried out apart from the periodic medical examination, if clinically or epidemiologically indicated.

In manufacturing areas, personnel with open cuts, wounds or burns shall be required to cover them with suitable water-proof dressings before starting operations. Any lost dressing must be reported to supervision immediately. The dressings should preferably be brightly coloured and metal detectable.

6.2 PERSONAL CLEANLINESS

Food handlers shall maintain a high degree of personal cleanliness and shall wear sufficiently clean and washable or disposable work clothing, (including headgear, nose mask, shoe cover and where appropriate, neck-covering and/or beard snood), to ensure that there is adequate coverage against perspiration from hair, beards, moustaches, etc. which cannot contaminate the product.

Where gloves are used for product contact, shall be clean, food grade (like nitrile etc.) and in good condition. Protective clothing mandated for use in manufacturing areas or hygiene purposes shall not be used for any other purposes.

Fingernails shall be kept clean without nail polish and trimmed.

Hand Wash notices shall be posted at appropriate places. All people entering food processing, storage, distribution and handling areas shall wash their hands with soap and potable water, followed by drying and sanitizing, where required:

- ✓ before starting work;
- ✓ after handling chemicals;
- ✓ after handling incompatible food products (for example, ingredients or work in process or finished goods) or contaminated materials;
- ✓ after breaks;
- ✓ after coughing or sneezing or blowing their nose; and
- ✓ after using toilet facilities.
- ✓ after using telephone / cell phones,
- ✓ after smoking in designated areas etc.
- ✓ Hand washing notices shall be posted at appropriate places.

6.3 PERSONAL BEHAVIOUR

The health supplement/ Nutraceutical manufacturer shall implement an effective personal hygiene programme that identifies hygienic behaviour and habits to be followed by personnel to prevent contamination of food.

Any behaviour or unhygienic practices like smoking, chewing or eating, sneezing or coughing over unprotected food, spitting, which could result in contamination of health supplement shall be prohibited in food processing, distribution, storage and handling areas.

Personal effects such as jewellery, watches, pins, perfumes or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

Personal lockers are to be provided to all personnel working in manufacturing areas to keep their personal belongings. Food contact tools and equipment's shall not be kept in personal lockers.

6.4 WORK WEAR & GROOMING

Personnel who work in, or enter into, areas where products and/or materials are exposed and are handled shall wear work clothing that is fit for purpose, clean and in good condition (e.g. free from rips, tears or fraying material). Clothing mandated for health supplement / Nutraceuticals protection or hygiene purposes shall not be used for any other purpose.

Work wear -

shall not have buttons, outside pockets above waist level.

shall be laundered at predefined intervals

shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.

Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints.

Personal protective equipment (PPE), where required, shall be designed to prevent product contamination and maintained in hygienic condition.

Protective Clothing used by a Health supplement Food Handler

6.5 VISITORS CONTROL

Visitors Policy can be implemented to ensure that visitors and contractors are asked to declare whether they have suffered or been in contact with any recent illness that may be a potential contamination risk to products, before they enter any manufacturing area.

Provision of clear information of any hygiene requirements specific to the product / manufacturing area should be displayed.

The Organization shall ensure that visitors to its manufacturing, processing or handling areas must wear appropriate protective clothing, footwear and adhere to the all the personal hygiene provisions required for personnel required in the food business.

Visitor identity cards provisions should be in place to maintain control on visitor's access into restricted areas.

7. SUPPORT SERVICES

Srl No.	Operational Area	Sub - Section No.	Topics
7.1	Management & Supervision	7.1	Management & Supervision
7.2	Sub Contracting of Operations	7.2.1	Terms of Agreement / Contract
		7.2.2	Technical Agreement
7.3	Quality Control & Testing Facilities	7.3.1	Specification & Test Methods
		7.3.2	Laboratory Personal
		7.3.3	Laboratory Facilities & Equipment
		7.3.4	Sampling Procedures
		7.3.5	Analysis and Validation
		7.3.6	Laboratory Documentation
		7.3.7	Control of Retention Sample
		7.3.8	External Laboratory
		7.3.9	Contaminants and Residues
		7.3.10	Calibration & Inspection of Measuring & Test Equipments
7.4	Pest Control Systems	7.4.1	General Requirements
		7.4.2	Preventing Access
		7.4.3	Harbourage & Infestation
		7.4.4	Monitoring & Detection
		7.4.5	Eradication
		7.4.6	Pest Control 4D
7.5	Cleaning & Maintenance	7.5.1	Cleaning & Sanitation
		7.5.2	House Keeping
		7.5.3	Storage of Cleaning Chemicals
		7.5.4	Maintenance
7.6	Waste Handling	7.6.1	Waste Removal
		7.6.2	Drainage System
7.7	Training	7.7.1	Awareness Training & Resource Management
		7.7.2	Training Program
		7.7.3	Refresher Training
7.8	Record Keeping	7.8.1	Audit, Documentation and Records – Self Inspection
		7.8.2	Manufacturing Documentation & Records
7.9	Consumer Awareness	7.9.1	Product Information & Labeling on Principal Display Panel
		7.9.2	Nutrition label Panel
		7.9.3	General Labeling
		7.9.4	Consumer Awareness
		7.9.5	Complaint Handling
7.10	Traceability & Recall	7.10.1	Traceability

		7.10.2	Recall Procedures
7.11	Stability Program	7.11	Stability Program
8.0	Implementation of Hazard Analysis & Critical Control Point Systems	8.1	Introduction to HACCP
		8.2	Application of HACCP System
		8.2.1	HACCP Implementation – 5 Steps & 7 Principles
		8.2.2	HACCP Implementation in Food Supplement Units
		8.2.2 A	Process Flow Chart for Powders
		8.2.2 B	Hazard Analysis for Powders
		8.2.2 C	Process Flow Chart for Liquids
		8.2.2 D	Hazard Analysis for Liquids
		8.2.2 E	Hazard Analysis for Tablets

7.1 Management & Supervision

Persons engaged in manufacturing, packaging, labelling, holding or in performing any quality control operations shall have the education, skill, training or experience to perform the assigned functions.

Managers and supervisors shall have necessary knowledge and skills to be able to judge potential risks and take necessary action to rectify any deviations.

The organisation management shall ensure providing necessary trainings & resources to their employees to develop food safety culture at plant.

Employees performing specialized job functions should be certified to a recognized industry standard or governmental organization (for e.g. pest control operatives etc.)

Standard operating procedure for GMP systems compliance should be maintained and its compliance shall be verified through records /checklists on routine basis. Records of Certification shall be verified.

Supervision by Managerial Staff

SOP's based on – 5W's & 1H are to be followed as :

Standard Operating Procedures

What is an **SOP ?**

It's a **"living" document** showing **Technical Instructions** of how to perform **routine** or **repetitive tasks**.

A "GOOD" Standard Operating Procedure

- Should provide all the information necessary to perform a task
- Is usually specific to the equipment used for the procedure
- Should be detailed
- Should "stand alone"
- Should provide quality control information
- Should provide references

7.2 SUB-CONTRACTING OF OPERATIONS

7.2.1 Terms of Agreement/ Contract

The contract between two parties is the Technical Agreement that accepts or shall ensure that the terms of the contract are clearly stated in writing and this shall include that:

Raw Materials, Intermediates & Finished Products shall be covered by detailed specifications. Any specific GMP requirements shall be clearly emphasized, and quality control, record transfer, coding rejection, dispute, and complaint procedures shall be identified & agreed.

Contractual conditions shall cover the following aspects to ensure quality standards and good manufacturing practice:

- Health supplement/ Nutraceuticals shall be produced safely within the manufacturing environment,
- To agree on a detailed product specification that covers all aspects of product, process, pack and delivery; this shall include the parameters to be used for acceptance or rejection, and any legal requirements,
- To agree on levels of sampling of finished products and sample plans to be used in case of dispute,
- To agree on the methods for determination of dates of expiration and the confirmatory documents,
- To evaluate the adequacy of the control resources, systems, methods and records of the manufacturer,
- To agree, wherever possible, objective methods of examination; subjective measurements should conform to recognised and accepted standards if possible,
- To agree the period for record keeping.

Any amendments or improvements shall be well documented and confirmation of acceptance of the completed work shall be recorded.

7.2.2 Technical Agreement

Technical agreement clearly defines the responsibilities of each party. Attention shall be given to clarifying the responsibilities of each party in relation to key/critical activities.

The scope of the instructions given by the Contract Giver to the Contract Acceptor, shall comprise:

- Approval and release of raw materials,
- Changes to the formulation and processes,
- Release specification,
- Release of the finished product and its transportation,
- The complaints and withdrawal and recall procedures,
- The procedure for notifying the Contract Giver of any abnormality during the contracted process
- Any dispute arising out of any non-conformity/non-conformances because of any reason should be settled appropriately.

Technical agreement may also include a section on the ownership of intellectual material (e.g. formulae, specific processing techniques), together with any restrictions

on the transfer of information to third parties. Items of possible confidentiality should be identified and any appropriate safeguards be mutually agreed.

7.3 QUALITY CONTROL & TESTING FACILITIES

Quality control programme shall be in place to include inspection and testing of incoming raw materials, process aids, ingredients, packaging material or any other material. Laboratory facility with trained and competent testing personnel shall be available for testings.

If there is no in-house laboratory present, all the regular testing shall be done through an accredited external laboratory/laboratory shall be notified by FSSAI.
In case of complaints or feedback on the product, the testings should be carried out either through their in-house/ external accredited labs/ lab notified by FSSAI to ensure product compliance to standards.
Test Records of raw materials, process aids, ingredients, packaging material or any other material /bulk chemicals test records shall be maintained. If pathogen testing is conducted in-house, microbiology laboratory shall not be open directly into process area.

Tested sample and remnant shall be autoclaved before disposing off.

Calibration of laboratory equipment shall be done periodically.

7.3.1 Specification and Test Methods

Authorized specifications for raw material, packaging materials, In-process material, Intermediate material and finished products should be maintained.
The specifications should include

- Description of the materials,
- Designated name of the material / product and the code reference
- Directions for sampling and testing
- Qualitative and quantitative requirements with acceptance limits
- Storage conditions and any special handling precautions
- Shelf-life

Validated methods should be used for testing of material / product.
Analytical method verification should be carried out for the compendia / pharmacopeia methods.
Scientific valid test methods published internationally (e.g. AOAC, BAM, USP, FCC etc.) can be used for testing and the manufacturer should affirm that the tests are accurate, precise and specific for its intended purpose.

7.3.2 Laboratory Personnel

Laboratory Personnel shall be appropriate in number with desired skill set.

All Laboratory personnel shall wear clean personal protective clothing appropriate to the tasks being carried out.

7.3.3 Laboratory Facilities and Equipment

All laboratory equipment and instrumentation shall be appropriate for the analysis required and shall be calibrated.

Written operating procedures shall be available for each instrument or equipment.

Quality Control laboratories should be designed and equipped to suit the operations required.

Sufficient space should be available for storage of chemicals, media, glassware, documents, samples and records,

Personnel operating the equipment shall be adequately trained.

Records of each service and calibration must be maintained for each equipment,

Adequate number of colour coded waste bins shall be provided for the collection of laboratory waste material prior to disposal.

Analytical methods shall include a control step to verify instrument or piece of equipment is functioning accurately.

7.3.4 Sampling

Sampling procedures shall be established and documented.

The following shall be included as a part of sampling procedure:

- The sampling equipment and type of sample container to be used
- The method and frequency of sampling
- Sample storage and handling requirements prior to testing, e.g. to minimise separation of mixed powders
- The quantity of sample required
- Any special precautions to be taken to maintain homogeneity of sample
- Instructions for any subdivision of the sample
- The cleaning and storage of sampling equipment and reusable containers

  Sample containers shall be clearly labelled with the contents, sample identification number, lot number and date sampled.

  Tables or notes used for calculation of the sample requirements shall be documented.

7.3.5 Analysis and Validation

Validation studies include processing, testing and cleaning procedures shall be an essential part of Good Manufacturing Practices, to be conducted as per the pre-defined protocols.

Validation parameters are:

- Specificity / selectivity;
- Recovery;
- Precision;
- Linearity and range;
- Accuracy;
- Limit of Detection (LOD) / Limit of Quantification (LOQ)

Details of Validation studies are to be recorded and retained.

Results of any sample analysis should be within the validated range of the methods used.

Personnel, premises, utilities, support systems and equipment should be appropriately qualified before manufacturing processes are validated.

Materials, environmental controls, measuring systems, apparatus and methods should be considered during process validation.

For process validation, normally, three batches are been considered as the acceptable number.

The number of batches should be justified and based on a risk assessment.

A written report summarizing recorded results and conclusions shall be prepared, documented and maintained.

Processes and procedures shall be established on the basis of validation study and undergo periodic revalidation to ensure that they remain capable of achieving the intended results.

Critical processes shall be validated.

When any new Master Formula or method of preparation is adopted, steps shall be taken to demonstrate its suitability for routine processing.

The defined process, using the materials and equipment specified shall be demonstrated to yield a product consistently of the required quality.

Significant changes to the manufacturing process, including any changes in equipment or materials that may affect product quality and/or the reproducibility of the process, shall be validated.

Validation of process shall be based on following protocols:

- ✓ Manufacturing conditions including operating parameters, processing limits and components.

- ✓ Type of testing or monitoring to be performed (in-process, release, characterization) and acceptance criteria for each significant processing step.
- ✓ Justified sampling plan, sampling points, sample size and the frequency of sampling for each unit operation and attribute.
- ✓ Details of the equipment and/or facilities to be used, including measuring or recording equipment.

Acceptable limits with details of methods for recording and evaluating results, including statistical analysis.



Analysis & Validation at Laboratories

7.3.6 Laboratory Documentation

Procedures shall be in place so that the data for all sampling, analysis and calculations are correctly recorded.

Records duly signed off shall be maintained for all tests and analysis performed in the laboratory.

Retention of laboratory documents, records and retained samples shall be done for a time period (preferable shelf life + 6 months) that is consistent with the requirements for the manufacturing records.

7.3.7 Control of Retention Samples

Retention samples of key raw materials and finished products should be stored in appropriate conditions and quantity.

Retention samples of finished products shall be stored in the same or simulated containers as per shelf life in which the finished products have been actually marketed.

7.3.8 External Laboratory

There shall be clear defined scope, details of services and responsibilities with contracted external Laboratory.

- External laboratories shall be nationally/ internationally accredited (ISO/IEC: 17025)

Trend analysis shall be carried out periodically on all analysis carried out by external laboratories, to ensure that there are no major trends or variations developing.

7.3.9 Contaminants and Residues

Chemical Contamination -

The unprocessed botanical and/or the botanical preparation should be tested for Heavy Metals (Lead, Cadmium, Mercury, Arsenic), Mycotoxins (Aflatoxins, Ochratoxin), NOTS, Pesticides residues.

Microbiological Contamination –

The unprocessed botanical and/or the botanical preparation should be tested for:

− Total Plate Count (Total Viable Count)
− Escherichia coli
− Salmonella spp.
− Entero bacteria
− Total combined Moulds/Yeasts

The test results shall be provided for each batch/lot.

7.3.10 Calibration and Inspection of Measuring and Test Equipment

All measuring and testing equipments shall be identified and labelled with their calibration status. All test equipment shall be identified with:

a) Item identity / Serial No.
b) Calibrated / Inspected Date
c) Calibration due / Inspection Due Date

Internal and external calibration schedule shall be maintained for all the equipments.

Calibration procedures shall have defined reaction plan if calibrated instrument fails calibration. The calibration instrument need to be traceable to a national standard (NABL accreditation).

7.4 PEST CONTROL SYSTEMS

7.4.1 General Requirements

Only nominated pest control technician or external pest management agency to manage pest control activities shall be allowed in the Plant premises.

Pest control program shall identify target pests and address plans, methods, schedules and control procedures.

Program shall include a list of chemicals which are approved for use in specified areas. Effective sanitation and Hygiene, inspection of incoming materials and monitoring can minimize pest infestation and thereby limit the need for pesticides.

7.4.2 Preventing access

Buildings shall be kept in good condition to minimize pest activity and to eliminate potential breeding sites.

Holes, drains and other places where pests are likely to gain access shall be sealed.

Windows, doors and ventilation openings shall be designed to minimize pest entry.

7.4.3 Harbourage and Infestation

Storage practices shall be designed to minimize the availability of food and water to pests. Ingredients and materials shall be stored above the ground and away from walls.

Items stored in the open at outer space, shall be protected from weather, pest damage, bird droppings.

Potential pest harbourage such as burrows, undergrowth, old & unused equipments shall be removed.

Infested Materials shall be handled in such a way so as to prevent contamination of other materials or products.

7.4.4 Monitoring and Detection

The entire manufacturing plant and surrounding areas must be regularly examined for pest activity.

Pest-monitoring program shall include the placing of detectors and/ or traps in key locations to identify pest activity.

A map of detectors and traps shall be maintained.

Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.

7.4.5 Eradication

The pest control treatment shall be carried out:

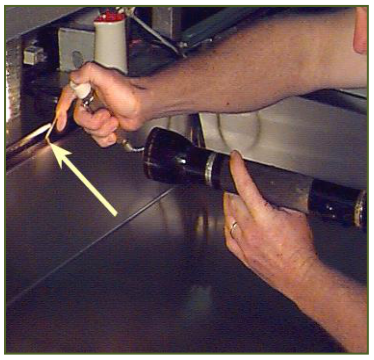
a) by trained personnel without posing a threat to the safety or suitability of health supplements/ nutraceuticals.
b) with permissible chemical, physical or biological agents, within the appropriate limits.

Records of pesticides / insecticides used shall be maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.

Pest infestations shall be dealt with immediately by a competent person.

The cause should be identified and corrective action taken to prevent reoccurrence.

In case of insect infestation area, appropriate fumigation should be done as per Plant quarantine Rules.

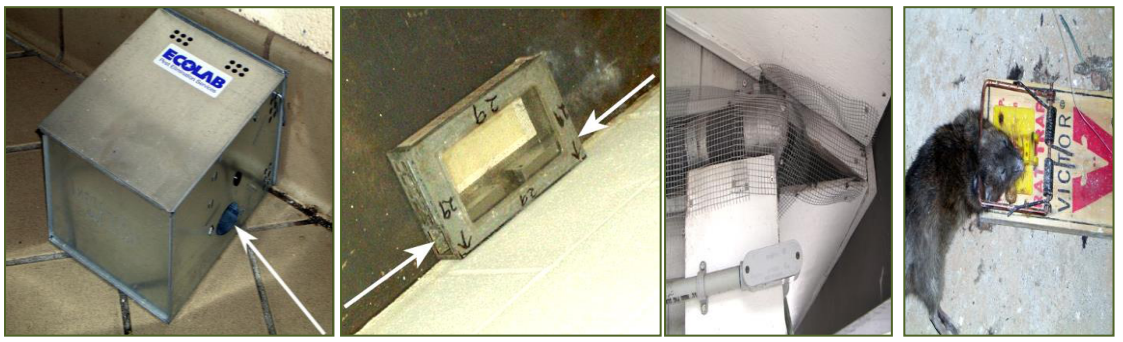


Chemical Control of Cockroaches

Treatment at cracks and crevices and spot treatment are done to

- Eradicate target pests
- Insecticides to be used at the minimum possible usage levels
- Avoid Contamination at preparation surfaces / equipment's
- Apply insecticides after working hours

Rodents Traps

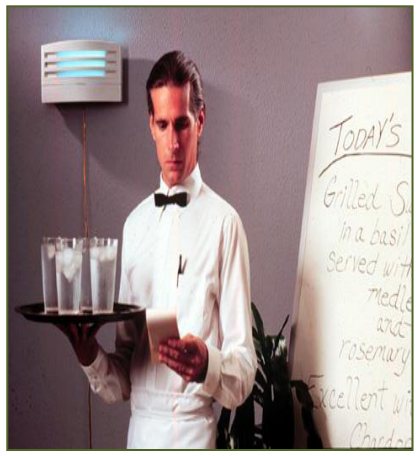


Mechanical traps are the best choice for indoor rodent control. Lethal traps include sticky traps (right) and regular snap traps (upper left). Mechanical rodent traps include "live traps" as shown here (lower left). Traps must be checked daily and rodents or their carcasses removed as soon as possible.

Rodent Baiting

Poison baits can be used outdoors and indoors. Placement of Baits are critical.
If baits are used indoors, rodents may die in a wall void, under appliances or in some other inaccessible place.
Rodent feeding activities on these baits are to be tracked.
As rodents prefer to travel along walls, so secured and numbered Bait Stations should be placed along the walls.

Light Traps for fly pests



Lights traps are helpful indoors and outdoors to trap flies.
They should be mounted preferably 4-6 feet off the ground, but out of the way of employee activities.
Indoor traps should not be visible from outside.
Otherwise, they might attract flies to the building.
Bulbs should be replaced yearly and the replacement date noted on the trap.

Pest Control Methods

•Rat cage protected by steel frame

•Glueboard for insect trapping in production

•maintain 1.5m radius gap

•End seal for pipelines not in use

•Insectocutor used outside production area

•maintain 3m radius gap

•Tamper resistant bait station secured onto ground

•hook up baits

•Mesh and grit for drainage

7.4.6 Pest Control - 4D Method

1D – Deny Entry- Preventing Entry	2D – Deny Shelter – Elimination of Harborage of Pests	3D – Deny Food- Eliminate food sources to pests	4D – Eradication of Pests
• Seal all holes, crevices at ceilings, walls and floors • Threshold clearances of doors < 6mm, fix metal kicking plates • Double door / air curtains / strip curtains / mesh screens, self-closing doors at appropriate locations Missing / damaged gratings of drains installed / replaced	• Avoid False sealing in processing and storage area • Repair defects on walls, floors, ceilings, woodwork & other structures • Remove disused / obsolete articles from food premises	• Store all foods and condiments in sealed / covered containers • Floor free from food remnants • Prohibit preparing food and utensils cleaning at other places • Store refuse in dedicated closed container and discard periodically to prevent accumulation. • Surface channels and gratings clean and clear of food remnants	• Clean & disinfect pest infested places, clothing and equipment • Use Insectocuter – Place 4.5 to 6 m away from food handling area • Use low wall mounted insectocutors • Clean insectocutor every week • Cover all foods during Pest control treatment • Use glue pads inside and rodent boxes outside the processing areas • Pest or chemical contaminated food be discarded.

Note:

Trend analysis of pests cited will help targeted pests in a focussed manner.

Safe use of pesticides to prevent cross-contamination is imperative.

Material safety data sheets of the chemicals used for pest control processes should be in place.

7.5 CLEANING & MAINTENANCE

7.5.1 Cleaning & Sanitation

Facilities shall have established Cleaning and sanitizing programmes. The programme should ensure that all parts of the establishment are appropriately and hygienically cleaned.

Food-processing equipment's and environment are maintained in a hygienic condition to prevent contamination of food.

Hygienic cleaning of Cleaning equipment's are to be done. Cleaning and disinfection chemicals shall be food grade only.

Manufacturers' instructions like, using the correct dilutions, storage norms are to be followed while handling and using cleaning chemicals and sanitizers to avoid the risk of contaminating food.

Removal of food residues and dirt can be done by physical and chemical methods of Cleaning / Cleaning agents.

The facilities should be constructed of corrosion resistant materials, easy to clean and shall have adequate supply of hot and cold potable water, where appropriate. It is recommended to have different colours for hot and cold pipes.

Hygienically cleaned Processing Equipments and maintenance of clean Environment

Master sanitation schedule shall be maintained for overall facility through checklists which includes :

- Areas, items of equipment and utensils to be cleaned;
- Responsibility for particular tasks;
- Cleaning method and frequency of cleaning;
- Monitoring arrangements for checking effectiveness of cleaning
- Person responsible for cleaning
- Persons responsible for monitoring & verification of effectiveness of cleaning
- In case of any deviation what correction & corrective actions are being taken.
- Chances of microbial risks are mitigated with product air count & swab tests.

A validation mechanism should be in place for establishing a cleaning programmes. Cleaning procedure should generally involve:

- Removing gross visible debris from surfaces.
- Applying a detergent solution to loosen soil and bacterial film (cleaning)
- Rinsing with water to remove loosened soil and residues of detergent.
- Dry cleaning or other appropriate methods for removing and collecting residues and debris
- Where necessary, cleaning should be followed by disinfection with subsequent rinsing.
- Designated area with lock & key provision should be allocated for cleaning equipment's & chemicals.
- Where ever necessary & applicable CIP procedures should be defined for equipment's cleaning.
- Cleaning effectiveness needs to be verified at regular intervals (e.g. swab test and others)

Sanitizing

- A process that reduces pathogenic organisms to acceptable level, applicable for decontaminating food contact surfaces.
- Sanitizers are substances capable of destroying microorganisms including those bacteria that cause food poisoning and other diseases.
- When used properly, they can reduce surface contamination by bacteria to a safe level.

It is important to read and follow the directions on sanitizers carefully. :

1. Some sanitizers are toxic and residue must be rinsed off.
   Toxic sanitisers include:

I. QACs (quaternary ammonium compounds)
II. chlorine release agents (hypochlorites)

2. Some sanitizers, such as chlorine dioxide, are safe for food and do not require rinsing.
3. Sanitizers all work best at the correct dilution. If they are too weak, they do not work effectively.
4. Sanitizers need time to work. The contact time varies and may be seconds or minutes depending on the job.
5. Sanitising solution can be made up as needed and put into labelled spray bottles for use on bench tops, fridges, door handles and other surfaces.
6. Check the dilution, contact time, safety precautions, shelf life and storage of all chemicals before use.
7. For effective use of a sanitizer, the manufacturer's instructions provided on the label are to be followed.

Types of sanitizers

There are two type of chemical sanitizers preferred by food industry and are as per International standard for sanitizing perishables and food contact surfaces.

i) Chlorine Based Sanitizer
ii) QMBA Sanitizer

Chlorine Based Sanitizers are generally preferred for sanitizing the perishables and QMBA Sanitizers are preferred for Food Contact Surfaces because Chlorine Sanitizers require continuous monitoring on its concentration due to their higher evaporation rates.

QMBA Sanitizer used for food contact surfaces because its concentration does not vary with time.

1. Residual Chlorine in water - 0.2 ppm (parts per million)
2. Chlorine for overhead water tank sanitization - 0.5 to 1 ppm

1. **Process of sanitization of perishable (e.g. botanicals)**
   - Wash with clean water
   - Sanitize with 100 –200 ppm of chlorine for minimum 30 sec
   - Rinse (wash again) with tap water containing 0.2 ppm of chlorine
2. **Process of sanitization of Food Contact surface**
   - Wash with clean water and detergent
   - Sanitize with 100 –200 ppm of QMBA sanitizer for minimum 3 minutes
   - Remove and dried before using

Storage of cleaning chemicals

Appropriate chemicals for cleaning/sanitizing

Chemical Dilution Rate Guide

How much chemical do I need to add?

For dilution ratios greater than 1:20, industry accepted rounded-off figures are given.

Dilution Rate Ratio	% of Chemical Required	Total RTU (ready to use) solution required			
		1Lt	5Lt	10Lt	20Lt
1:1	50%	500ml	2.5Lt	5Lt	10Lt
1:2	33%	333ml	1.67Lt	3.3Lt	6.6Lt
1:4	20%	200ml	1Lt	2Lt	4Lt
1:5	17%	166ml	833ml	1.66Lt	3.3Lt
1:9	10%	100ml	500ml	1Lt	2Lt
1:10	9%	90ml	454ml	910ml	1.8Lt
1:16	6%	60ml	300ml	590ml	1.18Lt
1:20	5%	50ml	250ml	500ml	1Lt
1:32	3%	30ml	150ml	300ml	600ml
1:40	2.5%	25ml	125ml	250ml	500ml
1:50	2%	20ml	100ml	200ml	400ml
1:64	1.5%	15ml	75ml	150ml	300ml
1:80	1.25%	12ml	62ml	125ml	250ml
1:100	1%	10ml	50ml	100ml	200ml
1:120	0.8%	8ml	40ml	80ml	160ml
1:200	0.5%	5ml	25ml	50ml	100ml
1:250	0.4%	4ml	20ml	40ml	80ml
1:300	0.3%	3ml	17ml	33ml	66ml
1:600	0.15%	-	8ml	17ml	33ml
1:800	0.125%	-	6ml	13ml	25ml
1:1000	0.1%	-	5ml	10ml	20ml
1:1200	0.08%	-	4ml	8ml	17ml

Always add water first and then chemical to avoid any splashes of concentrate and follow all chemical handling guidelines. Wear gloves, goggles and personal protection equipment as required. Read and understand the SDS & PIS of your chemicals before use.

Dilution of chemicals

Chemical Sanitizer	Concentration/ Contact Time
Chlorine	50 mg/L in water between 75 °F (24 °C) and 100 °F (38 °C) for 7 seconds
Iodine	Follow manufacturer's use directions; contact time at least 30 seconds
Quaternary Ammonium Compounds	Follow manufacturer's use directions; contact time at least 30 seconds

Contact Time of chemicals with surface

7.5.2 House Keeping

A housekeeping schedule covering manufacturing and storage areas shall be maintained.

The surrounding areas including roads, parking lots and drains should be well-maintained.

Walls and floors should be maintained neat and clean. Ceilings and light fixtures should be easy to clean. Drains should be sufficiently sized and well sloped. Drains should have removable grates installed for ease of cleaning.
For 3rd party (contract) cleaning companies, the supplier should define clear scope, details of services and responsibilities.
Waste storage areas should be clearly marked and waste shall be disposed of in a timely manner.

7.5.3 Storage and Handling of Cleaning Chemicals

Cleaning chemicals are not to be stored or left at / near Processing or Storage areas. To be kept under lock and key in a designated areas. Chemicals are to be stored in their originally labelled containers and ensured that they are closed properly.

Food storage containers are not to be used for storing, transporting or mixing of chemicals. The instructions on the labels are to be read and followed before use.

Two different chemicals are never to be mixed together.

Safety Posters or Graphics are to be displayed to alert employees on chemical safety precautions. Spraying of chemicals are to be done by holding the spray nozzle away from body. Protective gloves and goggles are to be used while handling Chemicals.

7.5.4 Maintenance

Maintenance workshops shall be separate and away from production areas. Spares, machine parts and tools are to be stored in dedicated rooms with lockers. Tools and spare parts, for the manufacture of products which are susceptible to microbial contamination, shall be disinfected before these are taken inside the production areas.

Preventive maintenance of equipment and machinery shall be carried out regularly as per the instructions of the manufacturer. The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards and cover the maintenance procedure, frequency and identification of the person (and/ or external agency) responsible for maintenance activity.
Internal & External calibration schedule for critical food safety equipment shall be maintained.
Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination and post maintenance verification shall be done.

Temporary fixes that put product safety at risk shall be removed / permanently fixed in a timely manner.

Lubricants, heat transfer fluids or any other similar material shall be food grade where there is no risk of direct or indirect contact with the product.

Plant equipment's breakdown records shall be maintained.

Loose items control policy (Nut & bolts, Nails broken pieces or smaller parts of machines) shall be followed to prevent any contamination with product or packaging material.

Template for Cleaning/Sanitation Program

Item	Frequency	Equipment and Chemicals	Methods	Responsible Person
Structure				
Floors	End of each day or as frequently as required	Brooms, damp mop, brush detergent and sanitizer	1. Sweep the area 2. Apply detergent and mop the area 3. Use scrub for extra soil 4. Rinse thoroughly with water 5. Remove water with mop	
Walls, window and ceiling	Monthly or as required	Wiping cloth, brush and detergent	1. Remove dry soil 2. Rinse with water 3. Apply detergent and wash 4. Rinse with water 5. Air dry	
Food Contact Surfaces				
Work Tables and sinks	After use	Wiping cloth, detergent and sanitizer	1.Remove food debris and soil 2.Rinse with water 3.Apply detergent and wash 4. Rinse with water 5. Apply sanitizer 6. Air dry	

7.6 WASTE HANDLING

7.6.1 Waste Removal

All wastes from Health supplement & Nutraceuticals processing / handling / packing shall be removed from time to time. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and free from animals and pests.

Pedal Operated refuse bins shall be placed at appropriate places with a proper cover and shall be emptied regularly. Refuse bins shall be washed daily with a disinfectant and dried before next use to avoid cross contamination.

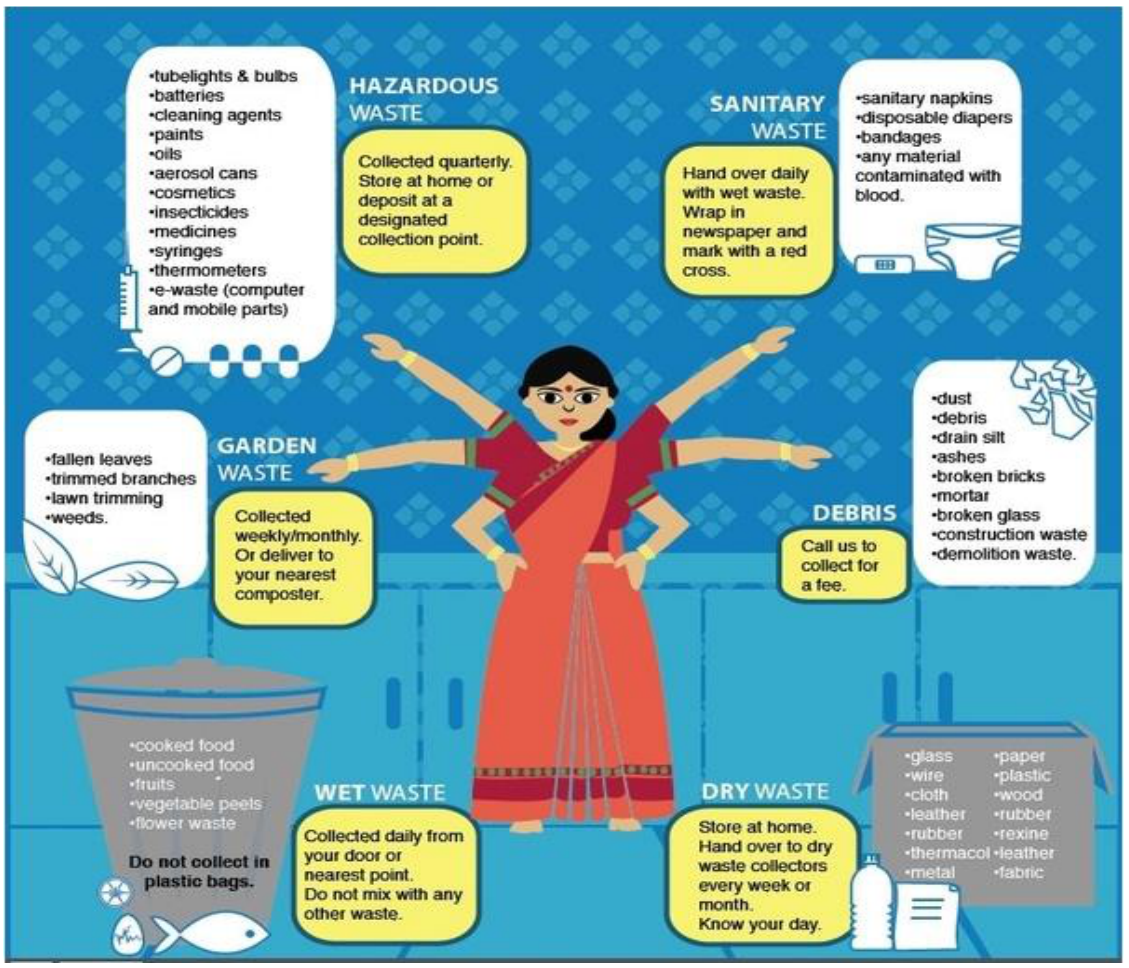
Segregation of non-biodegradable waste like plastics /metals / glass materials, bags, containers should be done, before disposal. Waste disposal shall be done in accordance with local rules and regulations in a hygienic manner.

Clean and sanitized, segregated waste bin system with lids and inner linings

Classification of Wastes

Bio-degradable - can be degraded (paper, wood, fruits and others)

Non-biodegradable - cannot be degraded (plastics, bottles, old machines, cans, Styrofoam containers and others)



Rationale
Waste is a potential source of pathogens and food contaminants. Proper disposal of waste is important for preventing the spread of pathogens inside food premises and contamination of food. Properly maintained waste containers can discourage the access of pests and animals

7.6.2 Drainage System

Adequate drainage and waste disposal systems and facilities shall be designed and constructed so that the risk of contaminating food or potable water supply is avoided. Drains shall be designed to meet expected peak loads, constructed so as to prevent accumulation or back flow of waste water. Drains should be located so that they can be easily and effectively cleaned and inspected. Drains shall be equipped with appropriate traps to effectively capture contaminants. The disposal of sewage and effluents (solid, liquid and gas) shall be as per the Factory/Environment Pollution Control Board requirements.

7.7 TRAINING

7.7.1 Awareness and Responsibilities

All personnel shall be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers shall have necessary knowledge and skills to enable them to handle food hygienically. Those handling strong chemicals or potentially hazardous substances shall be trained in safe handling procedures and techniques.

7.7.2 Training Programme

All personnel handling food are to be trained on Good Hygiene Practices and Good Manufacturing Practices.
Each new employee should receive training upon employment.
Training programmes shall be delivered by qualified and trained personnel.
Training for each employee can cover the following:

- ✓ As per Skill Matrix of the employee and Gap analysis on training needs;

- ✓ Particular tasks relevant to the employee's specific role; (e.g. allergens and allergen management protocols, cleaning and sanitation, pesticide application, GHP practices for the maintenance and internal audits covering personnel for regular and contractual employees)

Training process should be repeated, modified or extended as required. Training Program shall exists for all levels of employees of the organization (i.e. part- time, full-time, temporary staff, management, visitors, and contract personnel). Training procedures define short and long-term training requirements, retraining, refresher training, as well as the qualification steps (and experience level needed) for Trainers. When consultants are used for training, records of training are to be retained. Qualifications / Training experience of the Consultants are to be recorded. Training and qualification records shall be maintained for all personnel with relevant details like: Date, Topic, Name of Instructor, appropriate duration, Employee Signatures.
Periodic assessments of the effectiveness of training, instruction programmes are to be conducted to ensure that food hygiene and food safety procedures are well implemented by all trained personnel.

7.7.3 Refresher Training

Refresher Training programmes shall be routinely reviewed and updated wherever necessary. Systems shall be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of the products they manufacture.

7.8 RECORD KEEPING

7.8.1 Internal Audits

A Health supplement/ Nutraceuticals organisation shall undertake regular internal audits with a defined frequency of at least once a year, in order to check the implementation and compliance with GMP principles and to propose any required remedial actions.
These shall cover:

- Premises
- Equipment
- Production
- Quality control
- Distribution of the products
- Documentation
- Systems for dealing with complaints, withdrawals and recalls.

- Competent person(s)/ External experts shall conduct the internal audits in an independent way.
- The internal audit can include a check on absence of prohibitive substances in the raw materials.
- Agreed corrections and corrective actions shall be completed within a specified period of time.
- Training plan vs actuals
- Records shall be maintained of the observations made during the audit.
- Proposed actions are to be taken within relevant time frames.
- These records shall be retained for a pre-determined period of time.

Periodic audit of the whole system to ensure food safety

7.8.2 Manufacturing Documentation & Records

- The Manufacturing or Batch Records shall be checked at each level and approved by QA.
- Deviations shall be documented, justified and approved by QA.
- Manufacturing or Batch Records shall include the following:
- Bill of material (BOM), Manufacturing formula, Process flow chart.
- Manufacturing Instructions, Packaging list, Packaging Instruction, Labels etc.,
- Documentation for each significant step in the manufacturing process
- Written procedures for production line start-up, shutdowns and change-overs well defined.
- Following records shall be maintained by the FBO:
- Incoming materials checks – raw materials, ingredients, packaging materials.
- Inspection and testing
- Operational controls such as temperature, pressure, time etc.
- Product recall and traceability
- Storage

- Cleaning and sanitation
- Pest control
- medical examination and health status
- Training
- Calibration
- Complaints and customer feedback
- Internal audit records
- Corrective and preventive actions and others

7.9 PRODUCT INFORMATION & CONSUMER AWARENESS

7.9.1 Product Information and Labelling on Principal Display Panel

All packaged food products shall carry a label and requisite information as per provisions of Food Safety and Standards Act, 2006 and Regulations.

Adequate and accessible information on the product shall be available to each person in the food chain to enable them to handle, store, process, prepare and display the food products safely and correctly.

Information on food allergens if any in the product as ingredients shall be disclosed. Product identification / stages of processing / inspection and test status etc. so as to avoid their inadvertent use shall be made available.

The lot or batch no. can be easily traced and recalled if necessary. Lot identification shall be done to facilitate traceability, product recall, effective stock rotation etc.

Declarations on Principal Display Panel for all Health Supplements, Nutraceuticals, shall be as per FSSR 2011, Packaging & Labeling Norms (as amended) :

Clause No.	Section No.	Headings	Description of Requirements
FSS(HSN) 2016 - 6(3)(iii)(a)	7.9.1.1	Name of Category	Health Supplement or Nutraceuticals
FSS(HSN) 2016 - 6(3)(iii)(b)	7.9.1.2	Name of Food	Common name or description, true nature of food
FSS(PL) 2011 - 2.2.2.4 (i) - (iv)	7.9.1.3	Principal Display Panel	Declaration of Veg - Non Veg Logo
FSS(PL) 2011 - 2.3.2- 2.3.3 FSS(PL) 2011 - 2.2.2.7	7.9.1.4	Net Quantity	W.T , Volume, No., Size of Letters & Numerals
FSS(PL) 2011 - 2.2.2.2 and 5	7.9.1.5	List of ingredients	Declaration of Color, Flavor, Sweeteners & Allergens

7.9.2 Declaration on Nutrition Label Panel

Clause No.	Section No.	Headings	Description of Requirements
FSS(PL) 2011 - 2.2.2.3 (i)-(iii)	7.9.2.1	Nutrition Labeling	Serving References
FSS(PL) 2011 - 2.2.2.3 (v)		Nutrition Information	Declaration per serving accompanied by weight or volume in mg or (ml)
FSS(PL) 2011 - 2.2.2.3 (iv)	7.9.2.2	Nutrition Information	Amounts of Vitamins and Minerals in Metric Units
FSS(HSN) 2016 - 6(3)(iii)(c)	7.9.2.3	Nutrition Information	Amount of nutrients with nutritional or physiological effect
FSS(HSN) 2016 - 6(3)(iii)(e)	7.9.2.4	Nutrition Information	Percentage of nutrients with RDA (ICMR - Codex)

7.9.3 General Labeling

Clause No.	Section No.	Headings	Description of Requirements
FSS(PL) 2011 - 2.2.2.6	7.9.3.1	Name, Address. License No. & logo	Manufacturers & Packagers
FSS(PL) 2011 - 2.2.2.11 (i)(ii)	7.9.3.2	Country of Origin	Substantial change, Imported Food
FSS(PL) 2011 - 2.2.2.8	7.9.3.3	Batch/Lot/Code No	Declaration required
FSS(PL) 2011 - 2.2.2.9	7.9.3.4	Date of Manufacture / Packing	Manufacturing, packing
FSS(PL) 2011 - 2.2.2.10	7.9.3.5	Best Before or Expiry date	Durability - BBD or Expiry Date

7.9.4 Consumer Awareness

Information shall be presented to consumers in such a way so as to enable them to understand its importance and make informed choices. Information may be provided by labelling or other means, such as company websites, education programmes and advertisements, and may include storage, preparation and serving instructions applicable to the product.

Clause No.	Section No.	Declaration	For Health Supplements and Nutraceuticals
FSS(PL) 2011 - 2.2.2.12 (i)	7.9.4.1	Instruction for use	Serving tips, Heat, reconstitute,
FSS (HSN)2016 - 6(3)(iii)(e) FSS(HSN) 2016-7(4)(III)(d) (e)	7.9.4.2	Consumer Awareness	Recommended Dosage & Serving Size
FSS (HSN)2016 - 6(3)(iii)(d) (f)(g) (h) FSS(HSN) 2016-7(4)(III)(f)(g)(h)(i)	7.9.4.3	Advisories & Warnings	1.NOT FOR MEDICINAL USE, 2.Danger may exist with excess consumption 3. Health supplements not to be used as a substitute for a varied diet 4. Precautions, contradictions, product-drug interactions 5. Store out of reach of children

7.9.5 Complaint Handling

Manufacturers shall have a system to handle product complaints with identified person or people responsible for receiving, evaluating, categorizing, investigating and addressing complaints.

Complaints shall be accurately categorized according to safety concerns and other regulatory concerns, such as labelling and shall be investigated by appropriately-trained technical persons.

Documented procedures and trained personnel shall exist for customer complaint and AE (Adverse Event) investigation and response. Verification of customer satisfaction can be recorded after appropriate actions implemented. Regular complaint data analysis can be utilized to reduce future customer complaints.

7.10 TRACEABILITY & RECALL

7.10.1 Traceability

Established and applied traceability system shall be in place to enable identification of product lots and their relation to Batches of raw materials, Processing and delivery as per FSSAI regulations.

The facility/ system shall identify incoming materials from suppliers. It shall identify the initial distribution route for the end product. Records shall be maintained.

7.10.2 Recall Procedures

Organisation shall develop & implement food Recall Procedure in accordance with FSS (Food Recall Procedure) Regulations, 2017.There shall be a documented and effective product recall plan in place. Such a plan shall allow the organization to effectively locate all affected health supplement/ nutraceutical products that may cause a potential threat to public health and enable the complete, rapid recall of the implicated lot of the product from the market.

Where a product has been recalled because of an immediate health hazard, other products which are produced under similar conditions may also present a hazard to public health shall be evaluated for safety and may need to be recalled. Recalled products shall be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed / reworked in a manner to ensure their safety. The effectiveness of the Product recall procedure should be internally tested and documented at least once in a year. A recommended good practice is a Mock Recall.

Manufacturing records systems, distribution records systems and the marking of outer cartons and of individual packs shall be designed in a way that will facilitate effective withdrawal or recall, if necessary.

7.11 STABILITY PROGRAM

Stability program monitors the product over its shelf life and determines that the product remains within stipulated specifications under the labelled storage conditions.

The stability of the product shall be monitored according to a continuous appropriate programme that will permit the detection of any stability issue associated with the formulation in the marketed / consumer package. Though Stability Program applies to the product in Consumer packs only, in which it is marketed, but consideration shall also be given to the inclusion in the programme of bulk product.

Bulk products when stored for a long period before being packaged and/or shipped from a manufacturing site to a packaging site, the impact on the stability of the packaged product shall be evaluated and studied under ambient conditions.

Consideration shall also be given to intermediates of Bulk Products that are stored and used over prolonged periods. Stability studies on reconstituted products are performed during product development and are monitored. The stability programme shall be described in a written protocol and results formalised as a report.

The equipment used for the stability programme, e.g stability chambers, shall be qualified and appropriately maintained. The protocol for a stability programme shall extend to the end of the shelf life period and shall include the following parameters:

- ✓ Number of batches per strength and different batch sizes,
- ✓ Relevant physical, chemical, microbiological and biological test methods, stability indicating parameters,
- ✓ Acceptance criteria
- ✓ Reference to test methods
- ✓ Description of the container closure system(s)
- ✓ Testing intervals (time points)
- ✓ Description of the conditions of storage
- ✓ Other applicable parameters specific to the finished product
- ✓ The protocol for the stability program can be different from that of the initial long-term stability study as submitted in the marketing authorization dossier file.
- ✓ The number of batches and frequency of testing shall provide a sufficient amount of data to allow for trend analysis.
- ✓ Unless otherwise justified, at least one batch per year of product manufactured in every strength and every primary packaging type, shall be included in the stability program.
- ✓ Scientific justification has to be provided for the design of the stability program.
- ✓ A summary of all the data generated, including any interim conclusions on the programme, shall be written, maintained and periodically reviewed.
- ✓ International guidelines of ICH, WHO, USP etc., may be referred and recommended to practice.

8.0 SECTION C. IMPLEMENTATION OF HAZARD ANALYSIS & CRITICAL CONTROL POINT SYSTEMS

8.1 INTRODUCTION TO HACCP

Implementing Hazard Analysis and Critical Control Point (HACCP) is crucial for every Food Supplement Process. A HACCP plan covers the total supply chain, from inbound logistics, through storage, processing, sanitation and maintenance to the final use by the consumer.

Across the operations, it must be ensured that procedures are available for internal logistics, processing specifications, working instructions, hygiene procedures and preventive maintenance plans. These procedures cover start-ups, shutdown and unexpected stoppages during processing. HACCP sets a goal to minimize the associated risks during production and subsequently reduce unacceptable unsafe products.

Though HACCP system was designed to aim zero defect products, yet it is not feasible to achieve 100% defect free products. Hazard Analysis Critical Control Point (HACCP) is essential to carry out to identify the weakness of the production line and to suggest critical limits in compliance with legislation and therefore the preventive and corrective measures.

During implementation of HACCP, it is imperative to set controls at each point of the production line at which safety problems (physical, chemical and microbiological) are likely to occur. A HACCP plan is required to be in place before initiating the HACCP system. A HACCP Plan consists of 5 initial steps and 7 major Principles.

8.2 APPLICATION OF HACCP SYSTEMS

The requirements for Sanitation Standard Operating Procedures (SSOPs) along with Good Manufacturing Practices (GMPs) & Good Hygiene Practices should be considered as Pre-Requisite for HACCP. Risk assessment is a critical step in a HACCP plan. Below is a template to determine what severity and probability a processing step is involved with and therefore what level of criticality it holds in the processing line.

Probability/ Likelihood	What's the chance of the risk occuring?		Consequence/ Severity How severe could the outcome be if the risk event occurs?				
			Severe	**Major**	**Significant**	**Minor**	**Insignificant**
		Frequent	Extreme	Extreme	Very High	High	Medium
		Likely	Extreme	Very High	High	Medium	Medium
		Occasional	Very High	High	Medium	Medium	Low
		Seldom	High	Medium	Medium	Low	Very Low
		Unlikely	Medium	Medium	Low	Very Low	Very Low

Hazard Analysis and Critical Control Point (HACCP) decision trees are tools that are used to help decide whether a hazard control point is a critical control point (CCP) or not. A CCP is a step at which control can be applied. It is not always possible to eliminate or prevent a food safety hazard, so this allows you to reduce it to an acceptable level.

The purpose of a decision tree is to support the judgement of the team and help you to confirm whether the hazard needs more food safety controls.

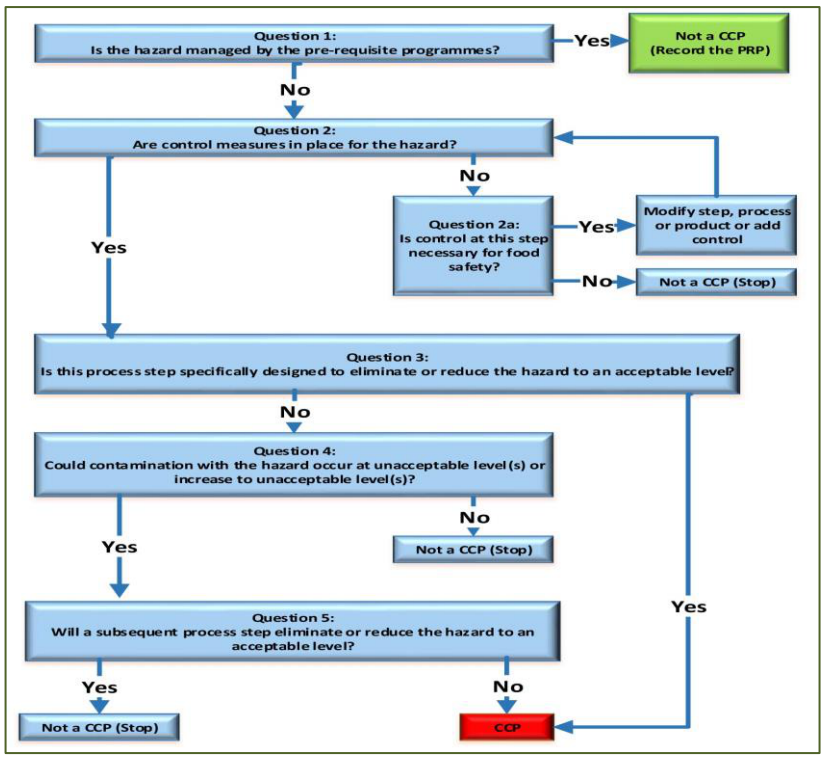
Decision trees are not mandatory elements of HACCP but can be useful in helping in determination of whether a particular step is a CCP or not. It is vital that the correct CCPs are determined to ensure that food is managed effectively and safely.

The number of CCPs in a process will depend on how complex the process is and how many hazards are present.

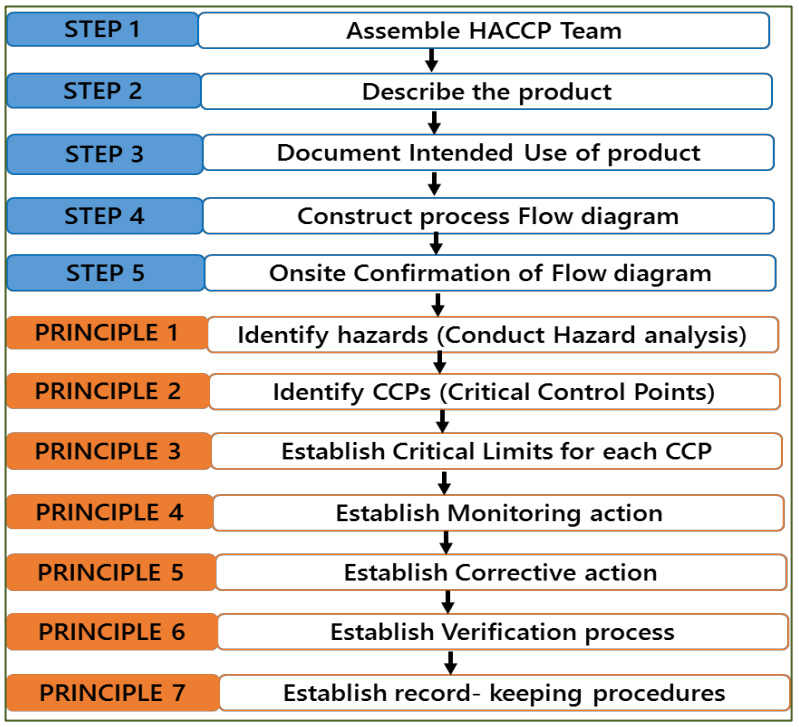
Introduction to Decision Tree

Decision trees are not mandatory elements of HACCP but can be useful in helping in determination of whether a particular step is a CCP or not. It is vital that the correct CCPs are determined to ensure that food is managed effectively and safely. The number of CCPs in a process will depend on how complex the process is and how many hazards are present. Hazard Analysis and Critical Control Point (HACCP) decision trees are tools that are used to help decide whether a hazard control point is a critical control point (CCP) or not. A CCP is a step at which control can be applied.

It is not always possible to eliminate or prevent a food safety hazard, so this allows you to reduce it to an acceptable level. The purpose of a decision tree is to support the judgement of the team and confirm whether the hazard needs more food safety controls.



8.2.1 HACCP Implementation: 5 Steps& 7 Principles



8.2.1.1 Assemble HACCP team

A multidisciplinary team shall be formulated in-house / on-site. Advice from experts can be obtained from other sources, to identify which segment of the food chain is involved and the general classes of hazards to be addressed.

8.2.1.2 Describe the Product

A full description of the product shall be drawn up, including relevant safety information such as composition (including raw materials ingredients, allergens), origin, physical/chemical properties that impact food safety (including Aw, pH, etc.),microbial/static treatments (heat treatment, freezing, brining, smoking etc.), packing, labelling, durability and storage conditions and method of distribution.

8.2.1.3 Identify intended use

The intended use of the product shall be defined based on the expected uses of the product by the end user or customer. The suitability of the product for vulnerable groups of the population such as pregnant women, infants, elderly should be considered, as necessary.

8.2.1.4 Construct flow diagram

The flow diagram shall be prepared to cover all steps in the operation for each specific product or product category. When applying HACCP to a given operation, consideration shall be given to steps preceding and following the specified operation.

8.2.1.5 On-site confirmation of flow diagram

Steps shall be taken to confirm the proceeding operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a competent person or persons.

On-site verification activities shall be carried out whenever there are any changes in the process.

8.2.1.6 List all potential hazards associated with each step, conduct a Hazard Analysis Study and consider any measures to control identified hazards (PRNCILPLE 1)

The HACCP team should list all potential hazards (physical, chemical, biological) that may be reasonably expected to occur at each step according to the scope. A hazard analysis study is to be conducted to identify the hazards which can be eliminated or reduced to acceptable levels as essential to the production of safe food.

In conducting the hazard analysis, the following should be included as appropriate:

- The likely occurrence of hazard and severity of their adverse health effects;
- The qualitative and/ or quantitative evaluation of the presence of hazards;
- Survival or multiplication of micro-organisms of concern;

- Production of persistence of foods of toxins, chemicals or physical agents with conditions.

Control measures are to be selected as required to be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure.

Where elimination of hazard is not practical, justification for acceptable levels of the hazard in the finished product shall be determined and documented.

8.2.1.7 Determine Critical Control Points (PRINCIPLE 2)

For hazards that requires control, control measures shall be identified. The control measures shall

be reviewed to identify those that need to be addressed through the HACCP plan and for which CCPs shall be identified. There may be more than one CCP at which control is applied to address the same hazard or there may be cases where there is no CCP identified. The CCP in the HACCP system shall be determined and this may be facilitated by a logic reasoning approach such as the application of a decision tree. The application of a decision tree should be flexible.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

8.2.1.8 Establish Critical Limits for each CCP (PRINCIPLE 3)

Critical Limits shall be specified and validated for each CCP. More than one critical limit may be elaborated at a particular step.

Critical limits shall be measurable and based on subjective data (such as visual inspection of product, process, handling) shall be supported by instructions or specifications and / or education and training.

8.2.1.9 Establish a Monitoring System for each CCP (PRINCIPLE 4)

A monitoring system shall be established for each CCP to demonstrate that the CCP is under control. The monitoring shall be able to detect loss of control at the CCP and in time to make adjustments to regain control of the process and prevent violation of the critical limits.

Where possible, process adjustments should be made when the results of monitoring indicate a trend towards loss of control at a CCP. The adjustment should be taken before a deviation occurs.

Data derived from monitoring shall be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring

is not continuous, then the amount or frequency of monitoring shall be sufficient to ensure that the CCP is under control. The monitoring system shall cover the following:

- ✓ Measurements or observations that provide results within an adequate time frame;
- ✓ Monitoring device used with applicable calibration method;
- ✓ Monitoring frequency;
- ✓ Responsibility and authority related to monitoring and evaluation of monitoring results;
- ✓ Records and documents associated with monitoring CCPs shall be signed;
- ✓ The monitoring methods and frequency shall be capable of determining deviations of CCP's.

8.2.1.10 Establish Corrective Actions (PRINCIPLE 5)

Specific planned corrective actions shall be developed for each CCP in the HACCP system in order to deal with deviations when they occur and to prevent their recurrence. The action shall ensure that the CCP has been brought under control.

Actions taken shall also include proper disposition of the affected product. Deviation and product disposition procedures shall be documented. Records of deviations and disposition shall be maintained.

8.2.1.11 Establish Verification Procedures (SEE PRINCIPLE 6)

The verification procedures consist of two activities, verification activities and validation activities.

The food business operator shall have in place a system to verify the HACCP plan at a set frequency. Procedures for verification shall be established. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions.

Where certain verification activities cannot be performed in-house, verification should be performed on behalf of the business by external experts or qualified third parties.

The HACCP system, including the HACCP plan, shall be reviewed (at least once in a year) and necessary changes made when any modification is made in the product, process, or any step. Verification activities shall include:

- ➢ Self-evaluation;
- ➢ Review of the HACCP system and plan and its records;
- ➢ Review of deviation and product dispositions; and
- ➢ Confirmation that CCPs are kept under control.

The results of verification shall be maintained and communicated to the HACCP team members.

The food business operator shall periodically validate the HACCP Plan. The objective of the validation process is to ensure that the identified hazards are controlled.

Validation activities should include actions to confirm the efficacy of the HACCP system.

Records of validation shall be maintained.

An annual review of the complete HACCP system shall be carried out.

Verification and validation activities are also important for maintenance of the system as well as continual improvements.

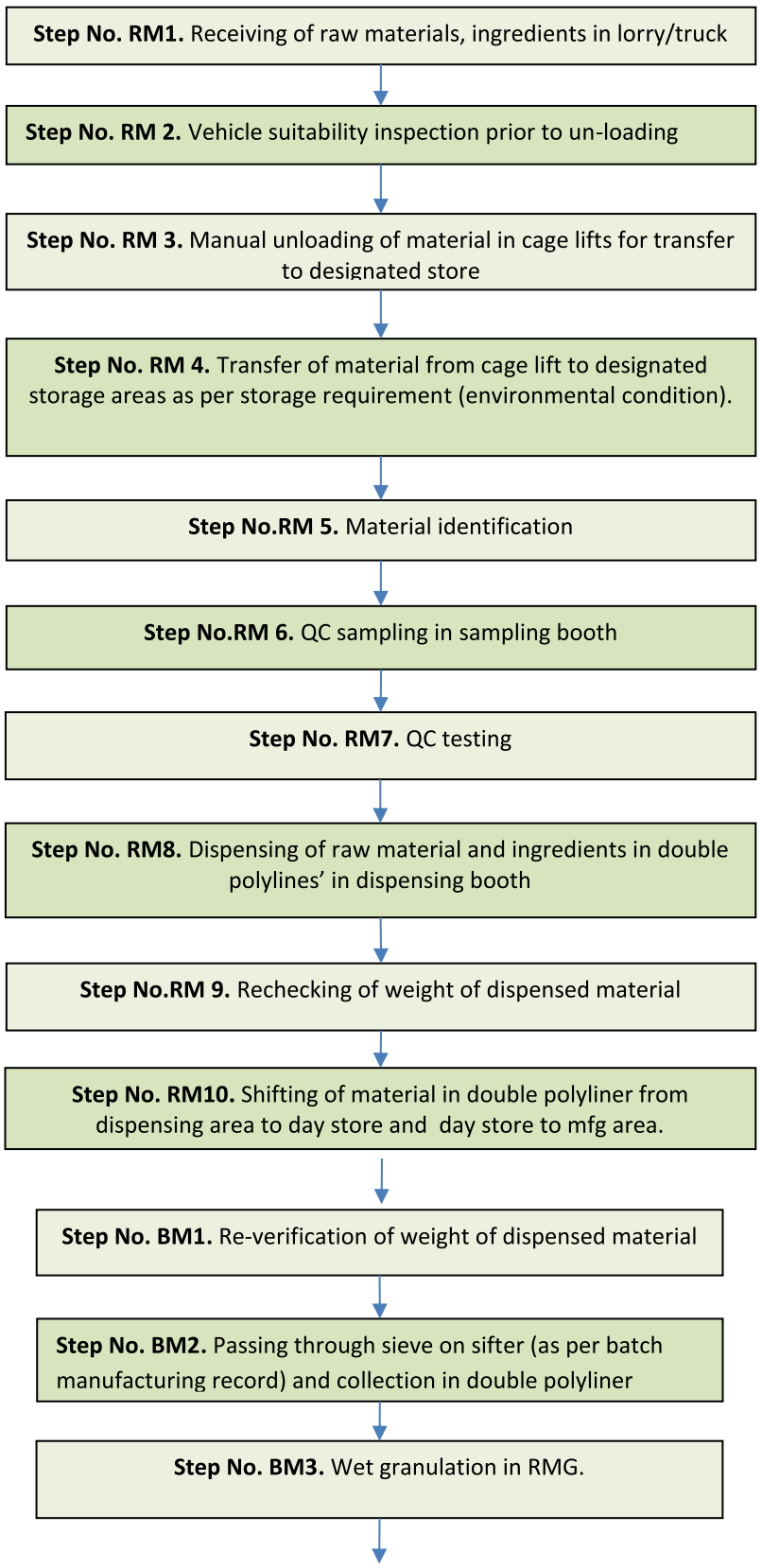
8.2.1.12 Establish Documentation and Record Keeping (PRINCIPLE 7)

HACCP procedures shall be documented. Documentation and record keeping shall be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Documentation shall include (as a minimum) the following:

- HACCP team composition;
- Product description;
- Intended use;
- Flow chart;
- Hazard analysis;
- CCP determination;
- Critical limit determination;
- Validation process; and HACCP plan
- The HACCP plan shall include the following information for each identified CCP:
- Food safety hazard(s) to be controlled at the CCP;
- Control measure(s);
- Critical limit(s);
- Monitoring procedure(s);
- Corrections and corrective action(s) to be taken if critical limits are exceeded;
- Responsibilities and authorities for monitoring, corrective action and verification;
- Record(s) of monitoring.
- Records to include
- CCP monitoring activities;
- Deviations and associated corrective actions;
- Disposition of non-conforming products;
- Verification procedures performed;
- Modifications to the HACCP plan;
- Validation record;
- Product release records; and
- Testing records

8.3 HACCP Implementation -- Process Flow Chart for Tablets



Step No. BM4. Drying in FBD

↓

Step No. BM5. Manual transfer of bulk material from double polyliner to blender for blending.

↓

Step No. BM6. Blending for time specified in batch manufacturing record → Rejection due to spillage (0.5%)

↓

Step No.BM7. Unloading of blend in double poly liners and label it.

↓

Step No. BM8. Transfer the blend in the commission room.

↓

Compression :----------

Step No. 1 Feed to hopper

↓

Step No. 2 Parameter setting as per BMR.

↓

Step No 03 Passing through metal detector → Rejection due to spillage & metal contamination (0.5%)

↓

Step No. 4 Collect compressed tablets & label it.

↓

Coating:----------

Step No. 1 Weigh the tablets

↓

Step No. 2 Set the parameters for coating.

↓

Step No. 3 In process check → Rejection due to spillage (0.5%)

↓

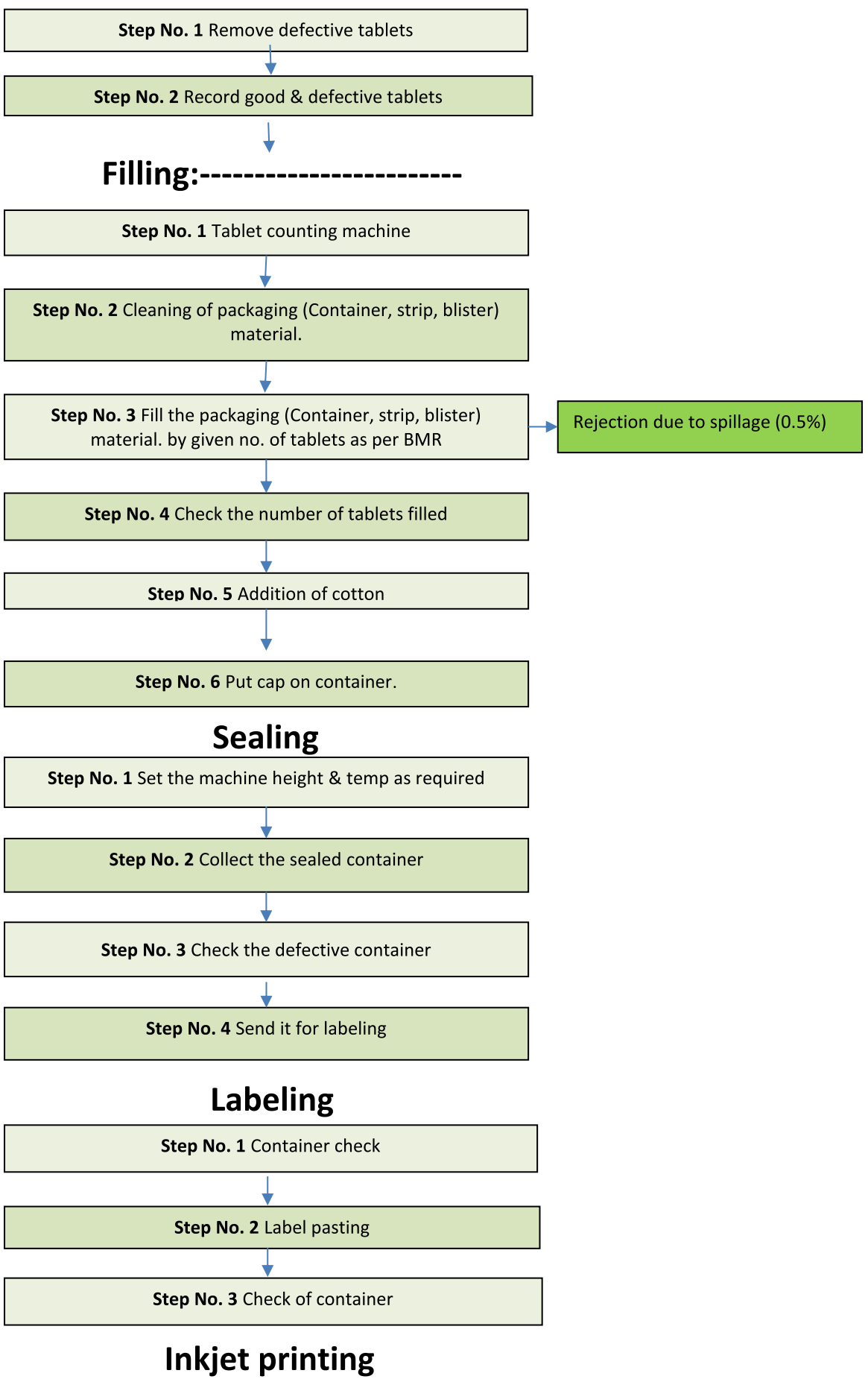
Step No. 4 Unloading from auto coater.

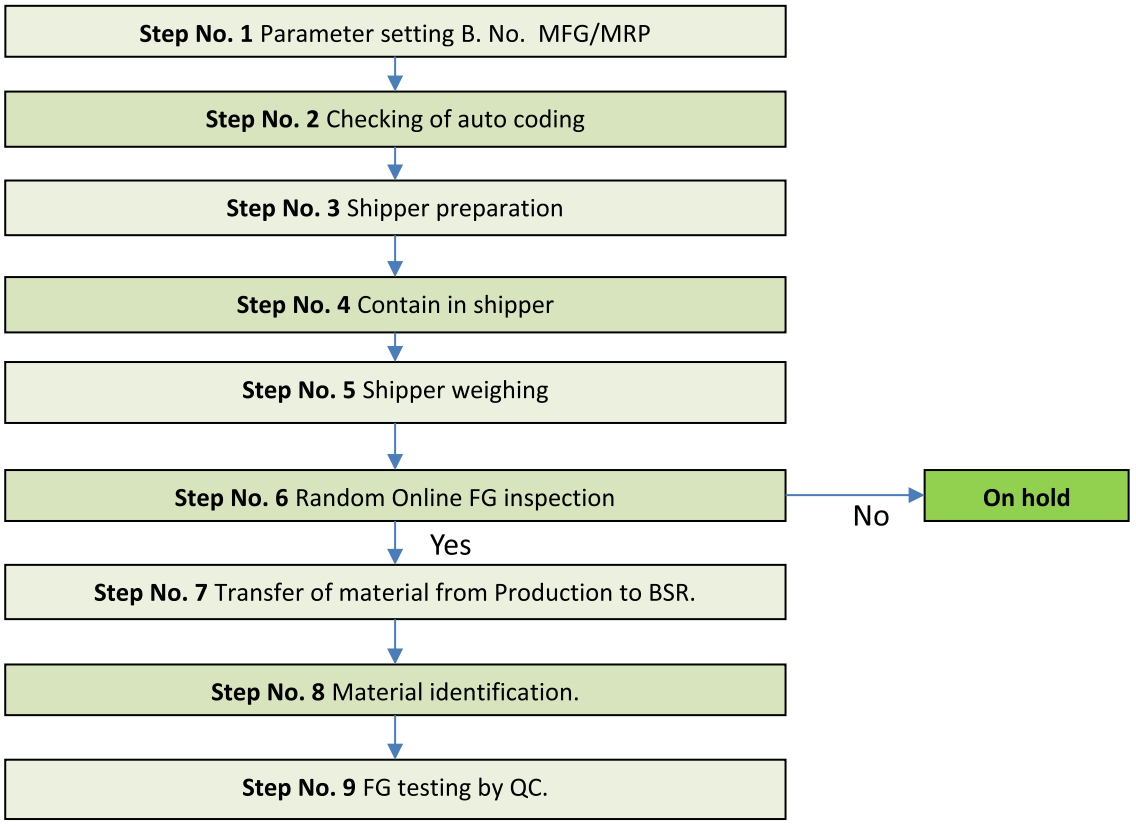
↓

Step No. 5 Weight the tablet & label it.

↓

Inspection:----------


Step No. 1 Remove defective tablets
Step No. 2 Record good & defective tablets
Filling:----------
Step No. 1 Tablet counting machine
Step No. 2 Cleaning of packaging (Container, strip, blister) material.
Step No. 3 Fill the packaging (Container, strip, blister) material. by given no. of tablets as per BMR
Rejection due to spillage (0.5%)
Step No. 4 Check the number of tablets filled
Step No. 5 Addition of cotton
Step No. 6 Put cap on container.
Sealing
Step No. 1 Set the machine height & temp as required
Step No. 2 Collect the sealed container
Step No. 3 Check the defective container
Step No. 4 Send it for labeling
Labeling
Step No. 1 Container check
Step No. 2 Label pasting
Step No. 3 Check of container
Inkjet printing


Step No. 1 Parameter setting B. No. MFG/MRP
Step No. 2 Checking of auto coding
Step No. 3 Shipper preparation
Step No. 4 Contain in shipper
Step No. 5 Shipper weighing
Step No. 6 Random Online FG inspection
No
On hold
Yes
Step No. 7 Transfer of material from Production to BSR.
Step No. 8 Material identification.
Step No. 9 FG testing by QC.

HAZARD IDENTIFICATION SHEET OF TABLET

Process step No.	Process step	Hazard			Why it is an hazard	(Likelihood of Occurrence)	Severity	Preventive Measures	Is further HACCP study required
		Type	Hazard	Source					
1	Receiving of raw materials, ingredients in lorry/truck	Physical	Foreign matter such as dust	Improper vehicle covering during transportation, RM bag bursting. Packing integrity compromised	It can lead to dental &GI injuries	Low	Minor	Physical inspection of each consignment & reject if not satisfactory use approved lot only. Vehicle suitability monitoring prior to unloading. Dedusting of unloaded material.	No
		Chemical	Hazardous chemicals	Transport vehicle when used for carrying chemicals. Chemical spillage.	It can lead to poisoning	Low	Minor	Vehicle suitability monitoring prior to unloading.	No
		Biological	Y&M and pathogens	Wet/torn bags, High moisture content due to improper covering of vehicle	It can lead to acute and chronic GI infections	Low	Minor	Vehicle suitability monitoring prior to unloading. Microbiology of RM/PM on receipt.	No
2	Vehicle suitability inspection prior to un-loading	Physical	None	-	-	-	-	-	-
		Chemical	None	-					
		Biological	None	-					
3	Manual unloading of material in cage lifts for transfer to designated store	Physical	Foreign matter such as dust	Due to unhygienic and unclean cage lift	It can lead to dental &GI injuries	Low	Minor	House keeping & personal hygiene procedures	No
		Chemical	None	-	-				
		Biological	None	-	-				
4	Transfer of material from cage lift to designated storage areas as per storage requirement (environmental condition).	Physical	Foreign matter such as dust, pest	Due to unhygienic and improper storage conditions and practices.	It can lead to dental &GI injuries	Low	Minor	House keeping & personal hygiene procedures	No
		Chemical	Pest infestation	Pest presence in stores	It can lead to poisoning	Low	Minor	Pest control procedure in place	No
		Biological	Y&M and pathogens	Due to improper environmental control for biologically sensitive material	It can lead to acute and chronic GI infections	Low	Minor	Biologically sensitive materials stored in environmentally controlled conditions	No

HAZARD IDENTIFICATION SHEET OF :----------

Process step No.	Process step	Hazard			Why it is the hazard	(Likelihood of Occurrence)	Severity	Preventive Measures	Is further HACCP study required
		Type	Hazard	Source					
5	Material identification	Physical	None	-	-	-	-	-	No
		Chemical	None	-	-	-	-	-	No
		Biological	None	-	-	-	-	-	No
6	QC sampling in sampling booth	Physical	Foreign matter such as dust, glass, metal	During sampling due to poor personal, equipment and environment hygiene practices. Poor re-packing of material after sampling.	It can lead to dental &GI injuries	Low	Minor	Personal hygiene, medical screening, equipment & sampling booth sanitation procedure in place.	No
		Chemical	Hazardous chemicals		It can lead to poisoning	Low	Minor	As a policy, material spilled on floor is to be discarded.	No
		Biological	Y&M and pathogens such as coliform		It can lead to acute and chronic GI infections	Low	Minor	Personal & equipment hygiene and microbiological verification of sanitation procedures. Use of protective clothing and gloves.	No
7	QC testing	Physical	None	-	-	-	-	-	No
		Chemical	None	-					
		Biological	None	-					
8	Dispensing of raw material and ingredients in double polyliners in dispensing booth	Physical	Foreign matter such as dust, plastic string, glass, metal	During dispensing due to poor personal, equipment and environment hygiene practices. Spillage due to poor dispensing & re-packing techniques. Use of plastic strings for tying polyliners.	It can lead to dental &GI injuries	Low	Minor	Personal hygiene, medical screening, equipment & sampling booth sanitation procedure in place. As a policy, material spilled on floor is to be discarded.	No
		Biological	Y&M and pathogens such as coliform		It can lead to acute and chronic GI infections	Low	Minor	Personal & equipment hygiene and microbiological verification of sanitation procedures. Use of protective clothing and gloves.	No
		Chemical	None	-	-	-	-	-	No

HAZARD IDENTIFICATION SHEET OF :----------

Process step No.	Process step	Hazard			Why it is an hazard	(Likelihood of Occurrence)	Severity	Preventive Measures	Is further HACCP study required
		Type	Hazard	Source					
9	Rechecking of weight of dispensed material	Physical	Foreign matter-Dust	Bag bursting, spillage due to improper handling	It can lead to dental &GI injuries	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners	No
		Chemical	None	-	-	-	-		
		Biological	Y&M and pathogens such as coliform	Due to high RH & environment biological load	It can lead to acute and chronic GI infections	Low	Minor		
10	Shifting of material in double polyliner from dispensing area to day store	Physical	Foreign matter such as dust, glass, metal	Bag bursting, spillage due to improper handling	It can lead to dental &GI injuries	Low	Critical	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners	Yes
		Chemical	None	-	-	-	-		
		Biological	Y&M and pathogens such as coliform	Due to high RH & environment biological load	It can lead to acute and chronic GI infections	Low	Minor		
11	Shifting of material in double polyliner from day store to manufacturing area	Physical	Foreign matter such as dust, glass, metal	Bag bursting, spillage due to improper handling	It can lead to dental &GI injuries	Low	Critical	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners	yes
		Chemical	None	-	-	-	-		
		Biological	Y&M and pathogens such as coliform	Due to high RH & environment biological load	It can lead to acute and chronic GI infections	Low	Minor		
12	Re-verification of weight of dispensed material	Physical	Foreign matter such as dust, glass, metal	Bag bursting, spillage due to improper handling	It can lead to dental &GI injuries	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners	No
		Biological	Y&M and pathogens such as coliform	Due to high RH & environment biological load	It can lead to poisoning	Low	Minor		
		Chemical	None	-	-	-	-		

HAZARD IDENTIFICATION SHEET OF :----------

Process step No.	Process step	Hazard			Why it is an hazard	(Likelihood of Occurrence)	Severity	Preventive Measures	Is further HACCP study required
		Type	Hazard	Source					
13	Passing through 20/30# sieve (as per batch manufacturing record) and collection in double polyliner	Physical	Foreign matter metal from sieve	Damaged Sieve mesh	It can lead to dental &GI injuries	Low	Major	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant , equipment and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners. Sieve integrity check. Rinse water test after cleaning of equipment	Yes
		Chemical	Hazardous chemicals	Residual cleaning chemicals.	It can lead to poisoning	Low	Minor		
		Biological	Y&M and pathogens such as coliform	High moisture levels during sifting. Unhygienic and unclean equipment	It can lead to acute and chronic GI infections	Low	Minor		
14	Manual transfer of sifted bulk material from double polyliner to R.M.G	Physical	Foreign matter such as dust, glass, metal	Un cleaned machine	It can lead to dental &GI injuries	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant, equipment and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners. . Rinse water test after cleaning of equipment	No
		Chemical	Hazardous chemicals	Residual cleaning chemicals	It can lead to poisoning	Low	Minor		
		Biological	Y&M and pathogens such as coliform	High moisture levels in processing environment. Unhygienic equipment	It can lead to GI infections	Low	Minor		
15	Shifting of material from R.M.G to F.B.D.	Physical	Foreign matter such as dust, glass, metal	Un cleaned machine	It can lead to dental &GI injuries	Low	Minor	, Equipment and personal hygiene. Rinse water test after cleaning of equipment.	No
		Chemical	--	-	-	-	-		
		Biological	Y&M and pathogens such as coliform	High moisture levels in unloading bowl. Unhygienic equipment	It can lead to GI infections				
16	Passing through sieve on sifter (as per batch manufacturing record) and collection in double polyliner record	Physical	Foreign matter metal from sieve	Damaged Sieve mesh	It can lead to dental &GI injuries	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene. Use of double polyliner to prevent bursting of bags. Use of food grade polyliners. Sieve integrity check.. . Rinse water test after cleaning of equipment	Yes
		Biological	Y&M and pathogens such as coliform	High moisture levels in processing environment. Unhygienic and unclean equipment	It can lead to poisoning	Low	Major		
		Chemical	Hazardous chemicals	Residual cleaning chemicals	It can lead to acute and chronic GI infections	Low	Minor		

HAZARD IDENTIFICATION SHEET OF :----------

Process step No.	Process step	Hazard			Why it is an hazard	Risk (Likelihood)	Severity	Preventive Measures	Is further HACCP study required
		Type	Hazard	Source					
17	Blending for time specified in batch manufacturing record	Physical	Foreign matter such as dust, glass, metal	Bag bursting, spillage due to improper handling	It can lead to dental &GI injuries	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant, equipment and personal hygiene. Use of food grade polyliners. . Rinse water test after cleaning of equipment.	No
		Chemical	Hazardous chemicals	Residual cleaning chemicals	It can lead to poisoning	Low	Minor		-
		Biological	Y&M and pathogens	Unhygienic and unclean equipment	It can lead to GI infections	Low	Minor		No
18	Compression at different station machine. Feed to hopper	Physical	Foreign matter-Dust of previous product	spillage due to improper cleaning.	It can lead to dental &GI injuries	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene check. Rinse Analysis Periodical Swab test ALC	No
		Chemical	Presence of previous traces	Unclearn Equipments	It can lead to poisoning	Low	Minor		No
		Biological	Presence of micro flora	High moisture levels in processing environment.	It can lead to dental &GI injuries	Low	Minor		No
19	Parameter setting as per BMR	Physical	Checking of thickness, DT, Friability, Hardness, weight	Uncalibrated instruments ,	Unpalatable	Low	Minor	In process calibrated instruments	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	-	-		

HAZARD IDENTIFICATION SHEET OF :----------

20	Collect compressed tablets & label it.	Physical	Foreign matter-Dust and Label	Uncleaned drums and improper labelling	It can be lead to dental. Gi injuries	Low	Minor	Proper cleaing of drums and identification of labels– Reanalysis and packing within 90 days	No
		Chemical	-Keeping quality for 90 days	Difference in Assay	Less effective to body	Low	Minor		No
		Biological	Keeping quality for 90 days	Increase in micro flora	Less immunity	Low	Minor		No
21	Coating Weigh the tablets	Physical	In proper gross weight	Improper balance calibration.	Improper coating	Low	Minor	Balance calibration .	No
		Chemical	-	-	-	-	-		No
		Biological	-	. -	-	-	-		No
22	Coating Set the parameters for coating	Physical	Foreign matter-Dust of previous product	Unclean Equipments	Unpalatable	Low	Minor	In process calibrated instruments Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment. Temperature less than 25°C and Humidity less than 50% RH. Plant and personal hygiene check. Rinse Analysis Periodical Swab test ALC calebrated instruments	No
		Chemical	Presence of previous traces	Unclean Equipments	Contamination	Low	Minor		-
		Biological	Presence of micro flora	Unclean Instruments.	It can lead to acute and chronic GI infections	Low	Minor		No
23	Coating In process check	Physical	Checking of thickness, DT, weight	Un calibrated instruments.	Unpalatable	Low	Minor	Uncalibrated instruments	No
		Chemical	-	-	-	-	-		-
		Biological	-	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No

HAZARD IDENTIFICATION SHEET OF :----------

24	Coating Unloading from auto coater	Physical	Foreign matter- Dust	Uncleaned drums	It can lead to dental & GI injuries	Low	Minor	Proper cleaning of drums.	No
		Chemical	-	-	-	-	-		-
		Biological	Keeping quality for 90 days	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
25	Coating Weight the tablet & label it	Physical	In proper gross weight	Improper balance calibration.	Improper coating	Low	Minor	Balance calibration .	No
		Chemical	-	-	-	-	-		-
		Biological	Keeping quality for 90 days	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
26	Inspection	Physical	Remove the defective tablets & its record	Improper identification of drums, Improper light	Unpalatable	Low	Minor	Proper identification of drums, Proper illumination	No
		Chemical	-	-	-	-	-		-
		Biological	-	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
27	Packing	Physical	Foreign matter- Dust	Un cleaned machine	It can lead to dental & GI injuries	Low	Minor	Proper cleaning of machine.	No
		Chemical	-	-	-	-	-		
		Biological	-	-	-	-			-
									No

HAZARD IDENTIFICATION SHEET OF :----------

28	Strip Coding	Physical	Undesired coding	Different stereo	Mix up of batches		Minor	Cross checking of each sterio print and Printed foil proof.	No
		Chemical	-	-	-	-	-		-
		Biological	-			Low	Minor		No
29	Carton Coding	Physical	Undesired coding	Different stereo	Mix up of batches		Minor	Cross checking of each sterio print and Printed foil proof.	No
		Chemical	-	-	-	-	-		-
		Biological	-			Low	Minor		No
30	Putting of strips in carton	Physical	Undesired no of strips	Negligence	Undesired pack size	Low	Minor	-Cross checking of each carton by weighing.	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	-	-		No
31	Shipper preparation & contain in shipper	Physical	Wrong coding of batch number	No verification .	Incorrect information on Label, Unpalatable	Low	Minor	Proper coding with identification.	No
		Chemical		-	-	-	-		-
		Biological	-	-	-	-	-		No
32	Weighing of shipper	Physical	Improper gross weight	Improper balance calibration.	Improper info	Low	Minor	Balance calibration. -	No
		Chemical	Presence of previous traces	-	-	-	-		-
		Biological	Presence of micro flora	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
33	Transfer of material from production to BSR	Physical	Wrong identification and number of shippers	. number of shippers and identification of batch	Unpalatable	Low	Minor	Proper identification and exact number of shippers	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	-	-		No
34	Material identification	Physical	Wrong identification	Improper identification.	Unpalatable	Low	Minor	Proper identification	No
		Chemical		-	-	-	-		-
		Biological		.					No

HAZARD IDENTIFICATION SHEET OF :----------

31	Shipper preparation & contain in shipper	Physical	Wrong coading of batch number	No verification.	Unpalatable	Low	Minor	Proper coding with identification.	No
		Chemical		-	-	-	-		-
		Biological	-	-	-	-	-		No
32	Weighing of shipper	Physical	Improper gross weight	Improper balance calibration.	Improper co	Low	Minor	Balance calibration. -	No
		Chemical	Presence of previous traces	-	-	-	-		-
		Biological	Presence of micro flora	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
33	Transfer of material from production to BSR	Physical	Wrong identification and number of shippers	. number of shippers and identification of batch	Unpalatable	Low	Minor	Proper identification and exact number of shippers	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	-	-		No
34	Material identification	Physical	Wrong identification	Improper identification .	Unpalatable	Low	Minor	Proper identification	No
		Chemical		-	-	-	-		-
		Biological		.					No

HAZARD IDENTIFICATION SHEET OF :----------

35	FG testing by QC	Physical	Checking physical parameter as per specification	Un calibrated parameters.	Unpalatable	Low	Minor	Improper calibrated instruments.	No
		Chemical	Presence of previous traces	-	-	-	-		-
		Biological	Presence of micro flora	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
36	Transport vehicle for suitability verification	Physical	Foreign matter-Dust	Improper vehicle covering during transportation, RM bag bursting. Packing integrity compromised	It can lead to dental &GI injuries	Low	Minor	Physical inspection of each consignment & reject if not satisfactory use approved lot only. Vehicle suitability monitoring prior to loading. Dedusting of loaded material	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	Low	Minor		-
									No
37	Dispatch	Physical	Identification	Non Identification	-. Desired material not dispatched	Low	Minor	Check each material with Production dispatch plan and Q.C release certificate.	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	Low	Minor		No

DETERMINATION OF RISK AND SEVERITY OF HAZARDS

1. (Probability of occurrence)

High > Likely to happen

Low > Not likely to happen

2. (Severity of each hazard)

High > will automatically result in unsafe product

Low > will not result in unsafe product

3. Determination of significance: Risk: a Function of (Probability of Occurrence) and (Severity of each hazard) and Exposure

HACCP PLAN (CCP)- Tablet

CCP No.	Process Step	Hazard	CCP	Critical Limit	Monitoring system					Corrective action plan	Recording format	Verification system			
					What	Where	How	When	Who			What	How	When	Who
CCP 01	Sifting of bulk through defined mesh size as per product nature (BMR, MFR & procedures)	Physical-Foreign matter	Sieve integrity (final sieving)	Sieve size and condition	Sieve condition	Pre-sifting	Visual Inspection	Pre & post sieving	Production & QA shift i/c	Replace the sieve and re-sift the bulk.	Product BMR & sieve monitoring record	Sieve monitoring record	Review of records	Twice in a year	FSMS Team
CCP-02	Passing through metal detector	Physical Metal pieces	Metal Detector	FE- 0.8mm, N. FE.-1.0mm SS-1.2mm	MD functioning	Metal detector	Use of standard test balls	Once in a shift	Production & QA shift i/c	Re-calibrate the metal detector. Re-pass the whole lot from last reading onwards.	Product BMR & Metal detector monitoring record.	Metal detector monitoring record	Review of records	Twice in a year	FSMS Team

HACCP PLAN (OPRP)- Tablet

S. No.	Process step	Hazard	Control point	Critical Limit	Monitoring system					Corrective action plan	Recording Format	Verification system			
					What	Where	How	When	Who			What	How	When	Who
1.	Shifting of RM through defined sieve (Pre sieving)	Physical	OPRP	Sieve integrity as defined in BMR, MFR &TTD	Sieve integrity	Shifter assembly	Visual Inspection	Pre & post sieving	Production & QA shift i/c	Replacement of damaged sieve.	Product BMR	Sieve Monitoring record	Review of records	Once in six month	FSMS Team
2.	Passing of tin/jar/bottle through UV tunnel.	Microbiological	OPRP	Intensity of UV light	Any breakage or damage in UV lamp	inspection	Visual inspection	Once in a shift	Production & QA shift i/c	Replacement of lamp	Product BMR	Scrutiny of records	Review of records	Once in six month	FSMS Team

IMPORTANT PROFORMAS

1. Mandatory Proformas

1.1 Medical Fitness Certificate for Food handlers

PERFORMA FOR MEDICAL FITNESS CERTIFICATE FOR FOOD HANDLERS

(FOR THE YEAR .....)

(See Para No. 10.1.2, Part- II, Schedule - 4 of FSS Regulation, 2011)

It is certified that Shri/Smt./Miss..... employed with M/s....., coming in direct contact with food items has been carefully examined* by me on date ..... Based on the medical examination conducted, he/she is found free from any infectious or communicable diseases and the person is fit to work in the above mentioned food establishment.

Name and Signature with Seal
of Registered Medical Practitioner /
Civil Surgeon

***Medical Examination to be conducted:**

1. Physical Examination
2. Eye Test
3. Skin Examination
4. Compliance with schedule of Vaccine to be inoculated against enteric group of diseases
5. Any test required to confirm any communicable or infectious disease which the person suspected to be suffering from on clinical examination.

2. Recommendatory Proformas

2.1 Approved Supplier List

S.No.	Item/Material Name	Location of Use	Primary Approved Supplier (Name & complete address)					Secondary Approved Supplier (Name & complete				
			Complete Address	*Contact Person*	*Contact No.*	*Email id*	*Fax*	*Complete Address*	*Contact Person*	*Contact No.*	*Email id*	*Fax*

2.2 Incoming Vehicle Inspection Record

Date of Incoming Vehicle:
Vehicle Type:
Material in Vehicle received:
Number of Persons accompanying Driver:

PARAMETER EVALUATED	REMARKS
Security lock	
Type of carrier (full covered/ Open Roof)	
Mode of covering products (in case of Open Roof)	
Overall Hygiene in the interior	
Overall Hygiene on the exterior	
Any sharp edges / points in the interior of vehicle	
Any pests detected	
Any grease /oil detected	

Authorized Singature

2.3 Incoming Material Inspection

Includes all type: *Raw materials, Ingredients, Food addiitives, Processing aids, Packaging materials, Cleaning and sanitation chemiclas, etc.*		
Material Name:		
Supplier Name:		
Identification/Location of Supplier:		
Quanity received:		
Pack size received:		
Material Receipt Date:		
Transport Mode:		
Rejected (Yes/No):		
Reason for Rejection:		
PARAMETER EVALUATED	**STATUS/RESULTS**	**Signature**
Temperature (Degree Celsius)		
Visual Inspection Condition (OK/Not OK)		
Packaging & Labelling Condition (OK/Not OK)		
Production Date/Shelf Life Date/Expiry Date		
Vehicle Inspection Condition (OK/Not OK)		
Quality Lab Results (If applicable)		
Certificate Of Analysis (COA) received (Yes/No)		
Remarks		
Clearannce Date		
Authorized Signatore		

2.4 Operation Log Sheet (Template for Temperature Control)

S.No.	Date	Time	Temp. Gauge Number	Specification / Range allowed	Actual Result	Remarks	Sign

2.5 Product Release Record

Name of Product:	
Date of Manufacturing:	
Time of Manufacturing:	
Batch/Lot No.:	
Best Before/ Expiry Date:	
Quality Acceptance	
Analytical	
Microbiological	
Sensory	
Others, if any	
Quality Lab signature	

2.6 Non-conforming Material/Product

HOLD: ☐ **REJECT:** ☐

Material Type:

Finished Product ☐ Raw Material ☐

In-Process Product ☐ Packaging Material ☐

Material Name:
Date of Manufacturing/Receipt:
Quantity of Manufacturing/Receipt:
Lot/Batch No.
Quantity used:
Lot/Batch No.
Quantity Hold:
Lot/Batch No.
Quantity Rejected:
Lot/Batch No.

Reason for Hold:
Reason for Rejection:

Corrective Action:
Preventive Action:

Remarks:

Signature:
QC Executive *Qualiity Manager* *Mfg. Manager*

2.7 Rework Record

Batch No	Date	Qty	Material	Source	Time	Finished Product

2.8 Outgoing Vehicle Inspection Record

Date of Outgoing Vehicle:
Vehicle Type:
Material in Vehicle to be dispatched:
Date of Manufacturing:
Time of Manufacturing:
Batch/Lot No.:
Number of Persons accompanying Driver:

PARAMETER EVALUATED	REMARKS
Security lock	
Type of carrier (full covered/ Open Roof)	
Mode of covering products (in case of Open Roof)	
Overall Hygiene in the interior	
Overall Hygiene on the exterior	
Any sharp edges / points in the interior of vehicle	
Any pests detected	
Any grease /oil detected	

Authorized Singature

2.9 Product Recall record

S.No.	Date of Complaint	Nature of Complaint	Results of Investigation	Product / Batches & quantity recalled	Mode of Disposal

2.10 Product Identification and Traceability

Traceability Detail Format

Product Description

Plant Name: Manufacturing Date:
Product Name: Manufacturing Time:
Pack Size: Batch/Lot no.:

Traceability Details

Investigation Date: InvestigationTime End:
InvestigationTime Start: Total Time Taken:

A. CIP Details

Equipment Name	CIP Details			Remarks
	Date	Time	Person responsible	

B.Ingredient Details

Material Description		Remarks
Name	Batch/Lot No.	

C. Water Treatment Details

Chemical/Material Description		Remarks
Name	Batch/Lot No.	

D. Primary Packaging

Material Description		Remarks
Name	Batch/Lot No.	

E.Manufacturing Details

Date	Shift	Cases Manufactured	CCP Compliance	Remarks

F. Analytical Details

Date	Shift	Analytical compliance%	Product blocked,if any	Remarks

G.Dispatch Details

Invoice No.	Date of Dispatch	Quanity Dispatched= Total produced-(Rejected+ Control samples+ Warehouse retained)	Dispatch Destination	Remarks

2.11 List of Monitoring and Measuring Devices and Records of Calibration

S.No.	Name of Equipment	ID.No.	Location	Range	Least Count	Frequency of Calibration	In house calibration Done On	In house calibration Due On	Remarks	Sign

2.12 Preventive Maintenance Schedule

S.No.	Name of Machine/ Equipment	Code/ Identification No.	Specification /Supplier	Location of place of the Machine/ Equipment	Frequency of check					Remarks
					Daily	Weekly	Monthly	Half Yearly	Yearly	

2.13 Preventive Maintenance Record

Machine/Equipment Name.:
Machine/Equipment No.:
Location:

S.No.	Maintenance Check Point	Frequency of check					Signature	Remarks
		Daily	Weekly	Monthly	Half Yearly	Yearly		

2.14 Pest Management Plan

Type of Pest	Mode of Control	Station (locations) monitored	Number designated	Frequency of Monitoring	Remarks

2.15 Pest monitoring record

Date	Type of Pest	Mode of Control	Station (locations) monitored	Number designated	Frequency of Monitoring	Clean (ok/Not ok)	Remarks	Sign

2.16 Monitoring of Personnel hygiene

Date:

S.No.	Employee Code	Employee name	Area of work	Hand wash, sanitize (and Gloves where necessary)	Clean & trimmed Nails	No open Wounds	No Jewellery	Covered Hair	Clean outer garments / protective clothing	Clean Shoes/ shoe covers	Infectious Disease / Skin infection / Allergy, if any	No Tobacco/ Smoking / Chewing	Overall Hygiene Status upon examination (Yes/No)	Action needed on non-compliance	Re-examination status (Yes/No)
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
14															

Jewellery *wrist watches, cufflinks, ear rings, glass bangles, stick bindis*

2.17 Customer/ Consumer Complaint Log

Complaint Number: _____

Date: _____ **Time recorded:** _____ ☐ **am** ☐ **pm**
Quality related: ☐ **Food safety related:** ☐

Customer Details
Customer Name: _____
Phone: _____
Address: _____ City: _____
State/Province: _____ Zip code: _____
Email: _____

Product Consumed
Product name: _____
Batch Code/Lot no.: _____
Package size: _____
Location purchased: _____
Date of purchase: _____ Date consumed: _____
How was the product stored? _____

Nature of Complaint

Foreign object	☐	Off/ Unsatisfactory Flavor	☐	Allergic	☐
Packaging	☐	Illness	☐	Others	☐

How many people consumed? _____ **Ages?** _____
Symptoms/Additional Problem Information:_____

Has the Customer
Seen a Doctor? Gone to Hospital?
Spoken to a public health? Contacted Regulatory Agency?

_____

Comments & follow up action
Feedback from client- Status or date finalized

2.18 Training Record

Date of Training:
Conducted By:
Subject of Training:
Brief summary of the subject:
Duration of Training:

S.No.	Name of person trained	Functional area	Remarks	Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

2.19 Training Effectiveness record

Date of Training:
Subject of Training:
Brief summary of the subject:

S.No.	Name of person trained	Functional area	Pre-evaluation result	Post-evaluation result	Effectiveness status (Yes/No)	Comment on effectiveness	Signature of trainee
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Effectivess can be based on: Improvement in quality of work, Improvement in work output, Behavioural change, Overall usefulness of training, etc.

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FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
Inspiring Trust, Assuring Safe & Nutritious Food