



FOOD SAFETY AND STANDARDS  
AUTHORITY OF INDIA

*Inspiring Trust, Assuring Safe & Nutritious Food*  
Ministry of Health and Family Welfare, Government of India

# GUIDANCE DOCUMENT FOOD SAFETY MANAGEMENT SYSTEMS

## FOOD INDUSTRY GUIDE TO IMPLEMENT GMP/GHP REQUIREMENTS



**FOOD SUPPLEMENTS**

# Food Supplements

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

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## Disclaimer

It is to be noted that this guidance document does not intend to replace any legal provision of Food Safety & Standard Act, 2006 & regulations thereunder. 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

This Guidance Document on Food Safety Management System (FSMS) is prepared with the intent to provide implementation guidance to food businesses (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 document 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 guidance 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 technical panel of FSSAI along with ReCHaN (CII and IADSA Initiative for Food sciences) team for developing this document.

**Pawan Agarwal – CEO, FSSAI**

# SCOPE

This document is applicable for food businesses involved in the Food Supplement sector. Food supplements include:

- a) Health Supplements
- b) Nutraceuticals
- c) Food for special dietary use, other than infants, and those products intended to be taken under medical advice.
- d) Food for Special Medical Purpose
- e) Functional Food
- f) Novel Food
- h) Food with added probiotic ingredients
- i) Food with added prebiotic ingredients
- j) Specialty food containing plant or botanical ingredients with safe history of usage

All the above product categories may or may not be handled by the same facility. Hence, based on the product category handled, a food supplement industry could use the guidance document accordingly as per the operations applicable to them. The document is divided into five main sections. The first section gives an overview of the food supplement industry in India along with the rising need for food safety in the sector. The second section contains guidance for implementation of good manufacturing practices and good hygiene practices as outlined in Part II of Schedule 4 of Food Safety & Standard (Licensing & Registration of Food Businesses) Regulation, 2011. The document has specified requirements where compliance is essential and obligatory for food businesses and in such cases the word “shall” is used. In addition, certain good practices are also strongly advised for food safety operation & in such case “should” is used.

The third section of this document is recommendatory in nature and provides the basic knowledge and criteria for implementation of Hazard Analysis and Critical Control Point (HACCP) system by the food businesses. This section includes the manufacturing flow chart & two tables: Hazard Analysis and HACCP Plans. Tables of Hazard Analysis is expected to help the industry to identify the food safety risks related to each processing step, to identify the Critical Control Points (CCPs) along with recommended corrective actions and other related information. Sample HACCP Plans have been taken from some established practising food supplement industries. These plans could be used as reference by the industry and modified or altered based on their operations.

The fourth section provides an inspection checklist for Food Business Operator to audit their facility & operations. The FBOs can evaluate themselves based on the indicative scoring. The last section gives important templates and forms which will be required by FBOs to maintain the records. This includes mandatory forms as prescribed by FSSAI & few templates for maintaining records of processes critical for food safety.

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## **A. OVERVIEW OF FOOD SUPPLEMENT INDUSTRY IN INDIA**



## A. OVERVIEW OF FOOD SUPPLEMENT INDUSTRY IN INDIA

The global nutraceutical industry, valued at US\$ 182.6 bn in 2015, is one of the fastest growing industries today and expected to expand at a CAGR of 7.3% from 2015 to 2021.

Currently, the United States, Europe and Japan account for most (93%) of the total global nutraceutical market. The market, however, seems to have attained maturity in all the three regions. Therefore, the nutraceutical industries across the world are now turning their attention to emerging markets like India.

The nutraceuticals industry in India is one of the rapid growing markets in the Asia-Pacific region. According to a recent report, the nutraceuticals industry in India is worth about \$ 2.2 bn and is projected to grow at 20% to \$6.1 bn by 2019-2020.

The popularity and growth of this industry can be attributed to consumers' increased inclination towards health and nutrition. Over the past decade, there has been a radical change in lifestyles of Indians. Adoption of fast foods and packaged foods and sedentary lifestyle, has led to an increase in the incidences of lifestyle diseases such as diabetes, cardiovascular diseases and obesity. As a result, Indian consumers, predominantly the higher socio-economic and upper middle class, are perceiving nutraceuticals as alternatives to prescription drugs. The usage of dietary supplements is not limited to fulfilment of the daily requirement of particular required nutrients, but consumers are also considering the functional health benefits of these supplements for prevention of diseases.

Furthermore, they have been showing a keen interest in products for boosting energy and improving their physical endurance and mental alertness.

As a result, dietary supplements hold the largest share in the market.<sup>3</sup> The Indian dietary supplement market is composed of over 500 participants. Vitamins and minerals supplement market is the most competitive with over 100 participants. Further, India is opening up its market to foreign players. This could lead to healthy competition in this sector.

To keep up with the growing competition, nutraceutical companies are focusing their energies in developing new product and innovative formulations and using proper advertising techniques to help consumers choose the right products.

Nutraceutical ingredients have typically been positioned as natural and healthy alternatives to allopathic medicines. However, one of the primary challenges being faced by these products is the difficulty in formulating these products using the right dosage form. Besides, flavour and fragrance masking, the dosage forms also need to increase the stability of ingredients in the final product. But lately consumers are seeking more variety and benefits from delivery methods beyond those possible through traditional (tablet and capsule) technologies. As a result, the formulator needs to work far harder to cater to

increasing consumer demands. As the nutraceutical industries look to carve a niche of their own and create a differentiated product, an important trend is the growth and diversity of new dosage formulations. As a result, traditional tablets and chewable are slowly being replaced by capsules, particularly liquid-filled capsules.

The shift toward capsule formulation is consumer driven. Consumers prefer dosage forms like capsules as they are easier to swallow. Capsules, especially liquid-filled capsules, are also considered to work faster and better. For nutraceutical companies, capsules make for an ideal formulation as it requires fewer excipients and manufacturing steps, enables faster development, and offers more formulation flexibility. In addition, capsule formulations offer brand recognition in a crowded nutraceutical products market.

Capsule technologies are also advancing with designs that provide superior protection of the ingredients through moisture protection, enhancing and preserving bioavailability and stability, and offering timed or targeted release of ingredients for maximum effect. One of the hottest trends in nutraceutical industry is use of innovative formulation for capsules. Encapsulation technology has made a lot of progress allowing multiple ingredients to be encapsulated in a single capsule. The novel formulations allow nutraceutical companies to incorporate liquids, pellets, tablets and powders in capsules.

## **B. PRE-REQUISITE PROGRAMMES**

# **I. ESTABLISHMENT – DESIGN AND FACILITIES**

## **1. Location and Surroundings**

- i. The Health Supplement/ Nutraceuticals 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 it is already existing, appropriate control measures shall be taken.
- ii. 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.
- iii. The manufacturing premise shall not have direct access to any residential area.
- iv. 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.
- v. 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.
- vi. There should not be any stagnant water surrounding the facility. Where buildings are surrounded by grassed or planted areas, a clear space should be provided between the grassed planted areas and the building. Such grassed/planted areas should be regularly tended and maintained.

## **2. Building Design, construction & Layout**

### **2.1 Building Design & Layout**

- i. Plant layout should be designed, constructed and maintained in order to facilitate good manufacturing and hygienic practices.
- ii. 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 raw from processed area to prevent any cross-contamination.
- iii. Sufficient space and proper placement of equipment's as is necessary for the maintenance of sanitary operations.
- iv. The plant 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.
- v. The manufacturer should demonstrate adequate controls (in terms of segregation of area) where there is manufacturing of products like Pre & Probiotics.
- vi. Designed, constructed and maintained to prevent entry of insects and rodents.



Fig. 1 Building Design & Layout

## 2.2 Internal Structures

### 2.2.1 Walls and Partitions

- i. They shall be soundly constructed of materials that are durable, cleanable, and 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).
- ii. Premises shall be free of flaking paint and plaster to prevent the accumulation of dust, minimise condensation, and shredding of particles.
- iii. Wall floor joints should be curved in processing and packaging areas to facilitate cleaning.
- iv. Wall and pillar guards (SS) should be used to avoid daily wear and tear of the surfaces.

### 2.2.2 Ceilings and overhead fixtures

- i. **Ceilings-**
  - Shall be maintained in sound condition and constructed of materials that are durable, cleanable, and impervious to food, grease and water with no toxic effect in intended use.
  - Shall be sealed to prevent the entry of dirt, dust and pests.
  - Shall be free from flaking paint or plaster.
- ii. **Overhead fixtures**
  - Shall be suitably protected so that they do not act as contaminants in case of breakage.

### 2.2.3 Floors

- i. Shall be non-slippery, sloped appropriately, to allow adequate drainage. The drainage shall flow opposite to the flow of manufacturing process flow.
- ii. Shall be maintained in good repair with no cracks and crevices.
- iii. 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 should be avoided. This causes slippery. Sweeping and mopping is more appropriate and cost effective.
- iv. The floor and the walls should not be damp or moist.

#### 2.2.4 Doors & Window's

- i. Shall have smooth, non-absorbent surfaces. Wooden doors are not recommended as it promotes mould growth, termites with ageing.
- ii. shall be easy to clean.
- iii. Shall be close-fitting and with suitable precautions to prevent entry of pests.
- iv. Gaps if any between the door and the floor should be closed with suitable material like rubber strips, polyurethane etc. to avoid pest entry.
- v. To ensure dust, insects, birds and animals to be kept out of the premises entry/exit points should be suitably protected with such as strip PVC/air curtains/ doors with automatic self-closing devices etc.
- vi. External opening windows, roof vents or exhaust fan, where present, shall be adequately screened to avoid any external pest ingress.
- vii. Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes should be so situated and constructed as not to cause contamination of health supplements/ Nutraceuticals. They should also be well maintained.

### 3. Equipment Design and Installation

- i. Equipment and containers that come in direct contact with food (including food contact surfaces) and used for food handling, storage, processing, packing shall be:
  - located, designed and fabricated so that it permits necessary maintenance and periodic cleaning.
  - kept in good order, repair and condition as to minimize any risk of contamination. These include free from cracks, crevices, open seams etc.
  - made of impervious, corrosion free material which do not impart any toxicity to the food material and shall be easy to clean.
  - shall be placed to achieve easy and effective cleaning of adjacent areas like floors, walls, ceilings and other surfaces.
- ii. Equipment, containers and piping should be clearly labelled and identifiable.
- iii. All openings such as manholes, inlets, outlets, draining out of points, etc. should be made such that they can be locked and/or effectively sealed.
- iv. Manufacturing vessels, pipework, and material handling equipment are well bonded and smooth to prevent material build up and promote sanitary conditions.
- v. Hygienic design features may include:
  - Pipes shall be sloped, with no dead-legs or right-angled bends,
  - Domed tops, curved sides, conical bases for vessels/tanks.
  - Flexible hoses shall have a smooth (not ribbed) internal surface and have fittings which are sanitary and easy to connect/disconnect hoppers
- vi. All utensils/ container containing food products shall be covered with a properly fitted cover/lid or with a clean gauze net/ any other material. This helps to completely protect food from dust, dirt, flies and other insects.
- vii. In case, the equipment & utensils are also used for purpose other than preparation of health supplements/nutraceuticals, adequate control measures shall be implemented such as cleaning, sanitization etc. to ensure avoidance of cross-contamination.

- viii. There shall be appropriate facilities for cleaning and disinfecting the food contact equipment and instruments, and wherever possible Clean-In-Place (CIP) should be adopted.
- ix. Defective equipment shall, if possible, be removed from production and quality control areas. If the equipment is such that they cannot be removed, they should be clearly indicated with their status.

## 4. Facilities/ Utilities

### 4.1 General

- i. The facilities are essential services that play a vital role to industry. Quality facilities and utilities provided like water, light, hygiene facilities etc. are a prerequisite for an effective food safety. Back-up systems and other parallel infrastructure systems can be planned for continuous & uninterrupted supply.
- ii. As Industry Best Practice 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.
- iii. Pipe-work, electrical fittings, ventilation openings and similar services lines shall be designed, fixed and constructed to avoid creation of recesses. Services lines shall be identified by colours and the nature of the supply and direction of flow shall be marked /indicated.

### 4.2 Water System

- i. Adequate supply of potable water shall be available to meet operational needs.
- ii. Water including steam/Ice used as a product ingredient or in contact with food of food contact surfaces or used for equipment and plant cleaning shall be potable.
- iii. Potable water quality shall be as specified in the latest edition of BIS standard on drinking water (IS 10500). Potable water shall be analysed at least semi-annually to confirm that it meets the requirements of this standard.
- iv. Where it is necessary to store water, storage facilities including the storage tanks and water pipes shall be adequately designed, made of material that is non-toxic, corrosion resistant material and periodic cleaned and maintained to prevent contamination and records of the same should be maintained. The tanks shall be covered to prevent access by animals, birds, pests and other extraneous matter.
- v. Where water filters are used, they shall be regularly monitored or effectively maintained.
- vi. Recycled water used in processing or as an ingredient shall not present risk of contamination. It shall be of the same standard as potable water.
- vii. Non potable water (for use in, for example, steam production, firefighting& refrigeration equipment and other similar purposes where it will not contaminate food) shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.
- viii. The material of construction of pumps, valves, storage and distribution skids shall be non-reactive, non-corrosive, non-leaching and sanitary in design.
- ix. Water lines (used in internal Cleaning & as ingredients) shall be clearly separated and identified from others. Color coding of separate pipelines for potable water and non-potable water is recommended.

### 4.3 Air Quality and Environment conditions

- i. Air quality and environment conditions recommended for various areas:
  - Material sampling / dispensing – 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% or as recommended by the supplier
  - Material / product contact area – ISO 8; Temperature should not be more than 25° C and Relative Humidity (RH) should not be more than 60%+/- 5% or as per product requirement.
  - Process equipment washing area – Should be negative pressure with respect to processing area.
  - Process equipment storage area - ISO 8; Temperature should not be more than 25° C and Relative Humidity (RH) should not be more than 60%+/- 5% .
  - Input material storage area – environment conditions as per recommendations of the supplier
  - Finished product storage area – as per the established stability studies
  - Microbiology Lab (inoculum handling) – ISO 8 with LAF ISO 5 (Dedicated AHU provided for Microbiological Lab); Temperature should not be more than 25° C and Relative Humidity (RH) should not be more than 60%+/- 5% .
  - Other Microbiological Testing Areas – ISO 8; Temperature should not be more than 25° C and Relative Humidity (RH) should not be more than 60%+/- 5%.
  - Analytical Laboratory – Temperature should not be more than 25° C and Relative Humidity (RH) should not be more than 60%+/- 5%

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

- ii. The air shall not flow from contaminated to clean areas, the ventilation systems shall be so designed.
- iii. Adequate Differential Pressure shall be maintained between different classified areas. Systems shall be accessible for cleaning, filter changing and maintenance. Recommended differential pressure in adjacent areas should be min 0.5 mm of Water Column (5-10 psi).
- iv. Air filters, exhaust and air intake ports shall be examined periodically for physical filter integrity.
- v. Periodic air quality monitoring shall be in place.
- v. 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 pre-decided conditions are maintained.

#### 4.4 Compressed air and other gases

- i. 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 (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for food contact use, filtered to remove dust, oil and water to ensure microbial quality and so shall be checked at least in a year.



- ii. It is recommended to have an oil free Compressed air system.

#### **4.5 Lighting**

- i. Adequate natural or artificial lighting shall be provided to enable the personnel to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading.
- ii. The intensity (that is, the lux level) should be adequate to the nature of the operation. Recommended lux level for processing areas) is at least 540 LUX, as per USFDA Food Code 2013.
- iii. Light fixtures shall be protected to ensure that materials, product or equipment are not contaminated in the case of breakages.

#### **4.6 Personnel Hygiene Facilities**

- i. Personnel hygiene facilities shall be available to ensure that an appropriate degree of personal hygiene can be maintained to avoid any cross contamination. Such facilities shall be suitably located & designated.
- ii. Facility shall have following facilities- hand washing, lavatories, changing facility, rest and refreshment room. Such facility shall be suitable located and designated.

##### **4.6.1 Hand washing facilities**

- i. Facility with shot and cold or suitable temperature controlled potable water with suitable hygienic means of drying hands can be provided in such a position that the employee must pass them when entering the processing areas. This will help employees to automatically get an alert for hand washing without a miss.
- ii. Where hot and cold water are available, mixing taps should be provided.
- iii. Hand washing notices shall be posted on walls near hand wash stations.
- iv. Non- Perfumed liquid soap should be used in dispensers to wash hands as soap bars are a potential source of cross contamination.
- v. The design of taps should be such that there is no hand contact after washing while closing the taps. Preferably, elbow or foot operated taps are used in food manufacturing units.

##### **4.6.2 Hand drying and sanitizing facility**

- i. Hand drier where installed should be in working condition at all the times during working hours.
- ii. 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.
- iii. Generally, and preferably, hand driers are considered better than paper towels based on cost efficiency and effectiveness.
- iv. The dustbins used to throw the used-paper towels, should be foot-operated. This avoids any direct hand contact (washed hands) to open the dustbin.
- v. Self-drying hand sanitizer should be provided and should be used after drying of hands. This is the next step of disinfecting hands after cleaning.

##### **4.6.3 Lavatories**

- i. Lavatories shall be separate from other areas and shall not be directly connected to the storage and manufacturing areas.

- ii. Sufficient number and separate toilets/urinals for male and female should be provided. Industry best practice of 1:25 is followed for facility: employee ratio.
- iii. Adequate supply of water should be provided in toilets and urinals. Potable water should be used at the toilet wash basin stations, as the employees may need to touch food items while in production areas.
- iv. All toilet facilities should be clean and sanitized at all times of the working hours.
- v. Toilets should be so designed so as to ensure hygienic removal of waste matter.
- vi. Toilets should be well lit and ventilated and should not open directly into food handling areas.

#### **4.6.4 Changing facilities**

- i. 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.
- ii. Separate areas should be provided for home personal clothes and company uniforms (in case there is a designated full uniform used by employees during processing).
- iii. Factory Footwear should be cleaned periodically and not to be used for external purposes

#### **4.6.5 Rest and refreshment room**

- i. Rest & Refreshment Rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas,
- ii. Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods.
- iii. Employees' own food shall be stored and consumed in designated areas only away from Process & storage area. Tiffin's and personal belongings also shall not keep in Lockers.

*Note: A display board mentioning 'Dos' and 'Don'ts' for workers should be posted in a prominent place inside the premises, in English or local language, for all to understand. This will help all the employees to maintain their alertness on good hygiene practices.*

#### **4.7 Drains and Waste Disposal**

- i. 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.
- ii. Drains shall be designed to meet expected flow 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.
- iii. All health supplement/ Nutraceuticals waste and other waste materials shall be removed from time to time from the places where food is handled, or processed or packed.
- iv. A waste bin should be placed in all appropriate places with a proper cover and shall be emptied regularly. The design of the waste bin shall be such that no hand touch is required. This avoids cross contamination chances. They shall be washed daily with a disinfectant and dried before next use.
- v. Drains shall be equipped with appropriate traps to effectively capture contaminants.

- vi. Wherever existing, scrap stores/yards are to be designed and managed in such a way as to enable them to be kept clean and free from animals and pests.
- vii. Segregation of non-biodegradable waste like plastics /metals / glass materials, bags, containers should be done, before disposal.
- viii. Waste disposal shall be done in accordance with specific requirements of the Factory Act / State Pollution Control Board requirements.

#### 4.7.1 Area Classification for Cleanliness

Introduction: movement of material and methods, low to high

**High care area:** The area where product/material is gets exposed, having controlled temperature, humidity and differential pressure .eg processing, primary processing area, filling, sampling, dispensing etc.

**Low care area:** The area where product/ material is not exposed like, Washing area, secondary packing area, Warehouse.

High care zone should be monitored for environmental conditions in respect to microbial loads.

## II. ESTABLISHMENT - CONTROL OF OPERATIONS

### 1. Supplier Approval and Food receipt

- i. Supplier Quality Development Programme laying down the criteria for selection, approval, review and ongoing approval should be implemented.
- ii. All raw material, process aids, ingredients consignments 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.
- iii. Raw materials received shall be according to the storage and processing capacity of the processing plant.
- iv. All raw materials and ingredients, wherever applicable, shall conform to all Standards laid down under the relevant regulations.
- v. All raw materials, ingredients and packing material and process aids, wherever applicable, shall be inspected and sorted before processing. The manufacturer shall have procedures in place to confirm that the incoming materials meet the documented specifications through certificate of analysis, visual inspection, laboratory testing, review of label for allergens etc.
- vi. Records of raw materials or ingredients or any other material used in processing as well their source of procurements shall be maintained for traceability.
- vii. It is recommended to have food grade certificates for applicable food processing aids from suppliers.
- viii. All bulk tankers/ containers receipt if any shall be checked for seal integrity / previous cargo / inspection checklist at the time of receipt (Suggested in Annexure 1).
- ix. All packaged raw materials shall be checked for 'expiry date'/'best before'/'use by date', packaging integrity and storage conditions.
- x. 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. Storage and Material Control

#### 2.1 General

- i. The buildings, grounds fixtures and equipment of product storage areas and vehicles loading & unloading bays shall be designed, constructed, adapted and maintained to facilitate the operations carried out in them and to prevent damage.
- ii. Raw materials, ingredients, packing material and finished goods shall be stored in clean, dry, well ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.
- iii. Materials and product shall be suitably stacked with due regard given to safety. Aisles should be kept clear and not used for temporary storage of materials.
- iv. Receiving and dispatch bays shall be provided for receiving of material and dispatching of finished product from the storage areas. These 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.

- v. Adequate spacing should be maintained between pallets to ensure sufficient ventilation.
- vi. Periodic visual checks should be made of all pallets, racks and other storage infrastructure, w.r.t structural integrity and infestations.
- vii. There should be a separate sampling & dispensing area in the warehouse.
- viii. Raw material and ingredients shall be stored as per the storage conditions mentioned on the label or as specified by the vendor. Printed packaging materials shall be stored in safe, separate and secured manner.
- ix. All materials and product should be clearly marked with their relevant Identification/Lot Number, to maintain the traceability.
- x. The identification marking should be easily accessible/visible even when the material or product is stacked.
- xi. Storage area temperatures shall be monitored.
- xii. 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.

## 2.2 Access to storage area

- i. Access to material and product storage areas should be restricted to those working in those areas and to other authorised persons.
- ii. A 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.
- iii. 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.
- iv. Insectocutors shall be installed in storage areas appropriately.

## 2.3 Damaged, Rejected & Recalled Goods

- i. Damaged goods should be placed in a designated place physically segregated from Good stocks and properly labelled.
- ii. 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.
- iii. 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) that relates to the oldest packet in the case.
- iv. 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.
- v. Records for such returned or recalled materials shall be properly maintained as per the FSSR recall regulation 2017.

## **2.4 Cleaning of Storage area**

- i. Effective cleaning of storage premises and equipment must be carried out at the defined frequency and using the methods and materials specified in well-designed cleaning schedules and procedures.
- ii. Cleaning standard operating procedures (SOPs) shall be defined and records demonstrating compliance shall be maintained.
- iii. Storage areas should be regularly inspected for cleanliness and good housekeeping.
- iv. Cleaning materials should be stored in a separate location in order to avoid contamination.

## **3. Health Supplement/ Nutraceuticals Processing**

### **3.1 General**

- i. Food processing operations, flow diagram and standard operating procedures shall be documented, implemented and displayed at particular operations site. Standard operating procedures for process changeover from one kind of product to another shall be maintained and implemented.
- ii. Food processing daily process critical parameters like temperature / vacuum etc. records shall be maintained with appropriate coding for traceability.
- iii. Intermediate in-process samples taken and tested for critical parameters and test results records shall be maintained. Personnel shall put on clean protective clothing including footwear and wash their hands before entering.
- iv. Cleaning schedule for equipment in the food processing sections shall be maintained to ensure entire operations are carried out in hygienic conditions.
- v. Systems shall be in place to prevent contamination of foods by foreign bodies such as glass, metal shards from machinery and dust. In manufacturing and processing, suitable detection or screening devices shall be used where necessary.
- vi. Access to processing area by outsiders shall be restricted or controlled. Where risks are particularly high, access to processing areas shall be only via a changing facility.
- vii. When Presence of any allergens identified in food ingredients and products, controls shall be put in place to prevent their presence in foods where they are not labelled. Where cross-contact cannot be guaranteed, consumers shall be informed.
- viii. In case steam is used directly on food during processing, the steam to be prepared from potable water.
- ix. All manufacturing operations shall be carried out under the supervision of authorised technical person. Each critical step in the process relating to the selection, weighing and measuring of raw material, addition during various stages shall be performed by trained personnel under the direct personal supervision of authorised technical person.
- x. Adequate space, preferably separated from processing areas, shall be provided for cleaning and storing mobile equipment and utensils including the storage of cleaning materials.

- xi. Incoming materials and finished products shall be quarantined immediately after receipt or processing, until they have been released for use or distribution.
- xii. Intermediate and bulk products purchased as such shall be handled on receipt as though they were starting materials.
- xiii. 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.
- xiv. 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 Manufacturing Requirements for Tablets/Capsules, Liquids, Powder/ Premixes**

### **3.2.1 For manufacture of dosage forms (tablets and capsules)**

#### **3.2.1.1 General**

Dust control systems shall be employed while processing of dry materials for dust control and avoid any cross-contamination.

- i. A process of Line clearance shall be implemented before various processes like dispensing, mixing, sieving, blending, compression, packing.
- ii. All raw materials and ingredients shall be tested and released prior to dispensing. Raw material shall be dispensed as per BOM (Bill of Material)
- iii. Air conditioning shall be provided wherever necessary to avoid any cross contamination during health supplement processing.
- iv. Care shall be taken that compressed air or air-extraction nozzles are kept clean and that there is no evidence of lubricants leaking into the product from any part of the equipment.
- v. Filters shall be installed in air extraction systems with discharge points to retain dust and protect the factory and local environment.
- vi. Material shall be protected against by particles of metal or wood. The use of metal detector is recommended. Wooden equipment should be avoided.
- vii. Screens, sieves, punches and dies shall be examined for wear and tear or for breakage before and after each use.
- viii. All ingredients for a dry product shall be sifted before use unless the quality of the input material can be assured.
- ix. 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.
- x. The maximum period of storage of the bulk materials shall be validated and specified.

#### **3.2.1.2 Sifting, Mixing, blending and Granulation**

- i. Ensure the integrity of sieves before and after the process of sifting.

- ii. Residues from sieving operations shall be examined periodically for evidence of the presence of unwanted materials.
- iii. Sieves and screens in the sieving equipments should be free from lead.
- iv. 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 only be used. Air entering the drier shall be filtered.
- v. Granulation and coating solutions shall be made, stored and used in a manner which minimizes the risk of contamination or microbial growth.
- vi. Sifting and blending equipments shall be fitted with dust extractors or air handling unit for control of dust.
- vii. Mixing time, temperature and ampere load and other key parameters shall be recorded in the batch manufacturing record.
- viii. Blending time and RPM shall be recorded in the manufacturing record.

#### **3.2.1.3 Compressions (Tablets)**

- i. For each compression run and in case of multiple compression points in a compression machine, sufficient individual tablets shall be examined at fixed intervals to ensure that a tablet from each compression station or from each compression point has been inspected for suitable pharmacopeia parameters like appearance, weight variation, disintegration, hardness, friability and thickness. The results shall be recorded in the batch manufacturing record.
- ii. Weighing equipments shall be calibrated for in-process monitoring of tablet weight variation. Procedures shall be in place for detecting out-of-limits tablets.
- iii. Tablets shall be de-dusted and shall be monitored for the presence of foreign materials besides any other defects.
- iv. Tablets shall be collected into clean, labelled containers.
- v. In-process control shall be employed to ensure that the products remain within specification.
- vi. Dust control systems shall be installed for tablets compression to avoid cross-contamination. Each compression machine shall be installed in separate cubicles unless the same product is being made on each machine or unless the compression machine itself provides its own enclosed air controlled environment.
- vii. During compression, samples of tablets shall be taken at regular intervals of not greater than 30 minutes or as appropriate to ensure that they are being produced in compliance with specified in-process specification. The tablets shall also be periodically checked for additional parameters such as appearance, weight variation, disintegration, hardness, friability and thickness and contamination by lubricating oil.
- viii. Labelling shall be done of all the in-process material, granules and tablets to prevent any mix up during compression process.
- ix. Rejected or discarded tablets shall be isolated in identified containers and their quality recorded in the Batch Manufacturing Record.

#### **3.2.1.4 Coating (Tablets)**

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



- ii. 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.

#### **3.2.1.5 Encapsulation - Capsules (Powder & Liquid Filled)**

- i. Capsules shall be stored under adequate environmental conditions which shall ensure their safety from the effects of excessive heat and moisture.
- ii. Industry best practise 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.

#### **3.2.1.6 Printing (Tablets and Capsules)**

- i. Tablets and capsules after printing shall only be released after approval from quality control.
- ii. Edible grade colours and suitable printing ink shall be used for such printing
- iii. 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.
- iv. This section can be shifted to Vendor Management section. Guidance required for edible grade colour.

#### **3.2.1.7 Packaging**

- i. Packaging material shall be tested and released prior to dispensing.
- ii. Line clearance shall be done before dispensing of packing material and before a new packing operation starts. It shall be ensured that all tablets, capsules or foils of the previous batch are removed before a new packaging operation starts. An independent check of the packaging equipment before operation is commenced can be maintained.
- iii. 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.
- iv. Uncoated tablets shall be packed on equipment designed to minimize the risk of cross-contamination. Such packaging shall be carried out in an isolated area.
- v. The package coming out of the machine shall be inspected for defects such as misprint, Nofill, cuts on the foil, missing tablets and improper sealing.
- vi. Outdated or obsolete primary packaging material or printed packaging material shall be destroyed and recorded. – packaging / storage.
- vii. As Industry best practice, 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 and check wares to check for empty packets and broken tablets.

### **3.2.2 For manufacture of liquids**

#### **3.2.2.1 Building and Equipment**

- i. 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.

- ii. 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.
- iii. The premises and equipment shall be designed, constructed and maintained to suit the manufacturing of Liquids. Equipment design shall be such as to prevent accumulation of residual microbial growth or cross-contamination.
- iv. Drainage shall be designed to avoid back flow. Drains should be shallow to facilitate cleaning and disinfecting. Drains shall be of adequate size and have adequate traps.
- v. Tanks, containers, pipe work and pumps shall be designed and installed so that they can be easily cleaned and sanitized.
- vi. The furniture used shall be smooth, washable and made of stainless steel.
- vii. Stainless steel or any other appropriate material shall be used for parts of equipments coming in direct contact with the products.

#### **3.2.2.2 Water Treatment**

- i. Water treatment systems operation 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. A flushing shall be done after any chemical sanitation. Water shall be demineralized (free from minerals) & should qualify Indian Pharmacopeia IP 14.
- ii. The water quality shall be monitored periodically for chemical and microbiological contaminants.

#### **3.2.2.3 Manufacturing**

- i. Manufacturing personnel shall wear non-fibre shedding clothing to prevent contamination of the product.
- ii. 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.
- iii. 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.
- iv. The homogeneity of emulsion shall be maintained by use of appropriate emulsifier and suspensions by using appropriate stirrer during filling.
- v. The primary packaging area shall have an air supply which shall be adequately filtered.

#### **3.2.3 For manufacture of powder**

- i. The manufacturing area environment conditions shall controlled. Air shall be adequately filtered and conditioned. Recommended air quality in the processing area is ISO 14644-1/2:2015 .
- ii. The entrance to the production area shall be through a suitable airlock. Outside the airlock, Insectocutors shall be installed.
- iii. The area shall be fitted with an exhaust system of suitable capacity to effectively remove vapours, fumes, smoke, floating dust particles.

- iv. The equipment used shall be designed and maintained to prevent the product from being accidentally contaminated with any foreign matter or lubricant.
- v. Primary packing should be done in a separate section.
- vi. No rags or dusters shall be used in the process of cleaning or drying the process equipment or accessories used. Water used in compounding shall be potable water.
- vii. Powders, wherever used, shall be suitably sieved before use.

### **3.3 Calibration and Inspection of Measuring and Test Equipment**

- i. 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
- ii. Internal and external calibration schedule shall be maintained for all the equipment,
- iii. Calibration procedures shall have defined reaction plan if calibrated instrument fails calibration.

## **3.4 Allergen Management**

### **3.4.1 Allergen handling**

Major Allergens are –

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

### **3.4.2 Allergen Control and Management**

- i. Display all the allergens at the relevant places in the processing and storage areas for awareness among all the employees. All raw materials that are allergens should be labelled with a tag that states “Allergen.”
- ii. ii. Maintain all ingredient flow during the manufacturing from non-allergen using areas to allergen using areas. This will help prevent cross-contamination. Preferably products containing non-allergen ingredients should run before the product containing allergic ingredients.
- iii. Store all allergic foods or ingredients 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 label.
- iv. Dedicated scoops, utensils shall be used for specific allergens. Thorough cleaning should be there between allergic containing product manufacture and non-allergic containing product manufacture.

- v. When production scheduling and cleaning operations are not performed between allergen containing production runs, allergen testing must be performed. For. E.g. ELIZA test kits are used to verify.

## **4. Health Supplement/ Nutraceuticals Packaging and Warehousing**

### **4.1 Health Supplement/ Nutraceuticals Packaging**

- i. The packaging materials used shall be able to provide protection to all Health supplements/ Nutraceuticals products to prevent contamination, damage. It shall be able to accommodate required labelling as laid down under the FSS Act & the Regulations there under.
- ii. Food grade packaging materials shall be used for all packaging materials coming in direct contact with the food.
- iii. Packaging materials like aluminium, tin and plastic shall conform to BIS standards as mentioned under the FSS Regulations.
- iv. Packaging materials shall be robust and secure enough to prevent spoilage and contamination during transit.
- v. 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.
- vi. Health supplement/ Nutraceuticals packaging materials shall be inspected before use to prevent using damaged, defective or contaminated packaging, which may lead to contamination of the product.
- vii. 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.
- viii. Packaging section shall always be considered high care 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.
- ix. All packaging equipment like weighing scale shall be calibrated on daily basis against certified standards & their records be maintained.
- x. 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.
- xi. Normally, filling and sealing shall be followed as quickly as possible by labelling. If it is not the case, appropriate procedure shall be applied to ensure that no mix-ups or mislabelling could occur.

### **4.2 Warehousing**

- i. All packed goods shall be stored 18 inch away from walls and shall be stored on pellets or other similar raised platforms (like racks, cupboards) and not stored directly on floor.
- ii. The warehouses shall be kept clean, ventilated and under hygienic condition to avoid pest infestation, dirt, dust, smell.
- iii. 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.

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

S.No.	Area	Pallets to be used	Remarks
1	Raw material storage area	Plastic / MS Pallets	MS- pallets must be free from rusting
2	Sampling booth	Plastic pallets	
3	Dispensing area	Plastic Pallets	
4	Processing area ( Day Store, Silo, blender, Feeding )	Plastic Pallets	
5	Filling area	Plastic Pallets	
6	Secondary packing	Plastic / MS Pallets	
7	Warehouse	Plastic / MS Pallets	
8	Primary Packing Materials	Plastic / MS Pallets	Dedicated storage for primary packing materials. Primary packing materials should not store intermixed
9	Secondary / tertiary packing materials	Plastic / MS Pallets/ wooden pallets	The wooden pallets must be in good state free from insect infestation, FBO must have periodic maintenance schedule in place.
<b>Note: It is Industry Best Practice to use Plastic pallets throughout the product processing chain.</b>			

## 4. Rework & Control of Non-Conforming Product

- i. A non-conforming product can be detected through customer complaints, internal defect findings, internal audits, external audits, incoming material inspection or simply during normal testing and inspection activities.
- ii. 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.
- iii. All Traceability records for rework shall be maintained.
- iv. Stored rework/non-conforming/market returned material shall be protected from exposure to microbiological, chemical or extraneous matter contamination.
- v. 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 defined.
- vi. 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.
- vii. Standard operating procedure should be defined and documented for handling any rework or non-confirming products.
- viii. Additional inspection of reworked/reprocessed in-process or finished product is required and documented.

## 6. Transportation and Distribution

- i. Adequate storage and transportation condition requirement shall be in place.
- ii. Conveyances and/or containers used for transporting Health supplements/ Nutraceuticals shall be kept clean and maintained in good repair condition to protect from contamination and shall be designed and constructed to permit adequate cleaning and/or disinfection.
- iii. 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.
- iv. A procedure should be established to deal with damage occurring when goods are in storage or distribution.
- v. Security precautions shall be established for deterring and preventing any tampering with goods in storage and distribution.
- vi. Any docks, railway sidings, bays, driveways, etc. within the factory complex should be kept free from accumulation of debris and spillage.
- vii. Fork lift and other trucks used within the storage areas should normally be battery driven or otherwise equipped to prevent fume or fuel contamination.
- viii. The dispatches of finished goods must follow FIFO or FEFO (First Expiry First Out) system.

## **7. Traceability and Recall**

### **7.1 Traceability**

- i. Established and applied traceability system shall be in place
- ii. It shall enable identification of product lots and their relation to Batches of raw materials, Processing and delivery.
- iii. The facility/ system shall identify incoming material from suppliers.
- iv. It shall identify the initial distribution route for the end product.
- v. Records shall be maintained.

### **7.2 Recall procedures**

- i. Organisation shall develop & implement Health Supplement Recall Procedure in accordance with FSS (Food Recall Procedure) Regulations, 2017.
- ii. There shall be a documented and effective product recall plan in place in accordance with the FSS (Food Recall Procedure) Regulations, 2017. 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.
- iii. Where a product has been recalled because of an immediate health hazard, other products which are produced under similar conditions which may also present a hazard to public health shall be evaluated for safety and may need to be recalled.
- iv. 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.
- v. 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.

- vi. 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.

## **8. Quality Control& Testing**

- i. Quality control programme shall be in place to include inspection and testing of incoming raw materials and finished products.
- ii. Laboratory facility and trained and competent testing personnel shall be available for food testing. If there is no in-house laboratory present, all the regular testing done through an accredited external laboratory/laboratory shall be notified by FSSAI. In case of complaints or feedback on the product, the FBO shall carry out the testing either through their in-house/ external accredited labs/ lab notified by FSSAI to ensure product compliance to standards.
- iii. Incoming raw materials / Bulk chemicals / Ingredients test records or COA shall be maintained.
- iv. 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.
- v. Calibration of laboratory equipment shall be done periodically.

### **8.1 Specification and Test Methods**

- i. Authorized specifications for raw material, packaging materials, In-process material, Intermediate material, and finished products should be maintained. The specifications should include;
  - A description of the materials,
  - The 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
- ii. Validated methods should be used for testing of material / product. Analytical method verification should be carried out for the compendia / pharmacopeia methods. Scientifically valid test methods published internationally (e.g. AOAC, BAM, USP, FCC etc.) can also be used for testing and the manufacturer should affirm that the tests are accurate, precise and specific for its intended purpose.

### **8.2 Laboratory Personnel**

- ii. Personnel shall be appropriate in number with desired skill set.
- iii. All personnel shall wear clean protective clothing appropriate to the tasks being carried out.

### **8.3 Laboratory Facility and Equipment**

- i. 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.
- ii. Quality Control laboratories should be designed and equipped to suit the operations required.
- iii. Sufficient space should be available for storage of chemicals, media, glassware, documents, samples and records,
- iv. Personnel operating the equipment shall be trained
- v. Records of each service and calibration must be maintained for each equipment,
- vi. Adequate waste bins shall be provided for the collection of laboratory waste material prior to disposal.
- vii. Analytical methods shall include a control step to verify instrument or piece of equipment is functioning accurately.

## 8.4 Sampling

- i. 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
- ii. Sample containers shall be clearly labelled with the contents, sample identification number, lot number and date sampled.
- iii. Tables or notes used for calculation of the sample requirements shall be documented.

## 8.5 Analysis and Validation

- i. Written procedures shall be in place for the preparation of the reagents to be used in the analysis. Reagents and Reference standards shall be clearly labelled with the following information:
  - date of receipt or preparation,
  - their concentration,
  - standardisation factor,
  - shelf life
  - storage conditions
- ii. Reference standards and any secondary standards prepared from them should be stored, handled and used according to instructions.
- iii. Samples shall be analysed according to written procedures, using test methods which are either legally required or are internationally accepted, or other methods that have been scientifically validated for the required sample matrix.



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

Validation shall include the following parameters:

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

Validation details shall 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. Traditionally, three batches have been considered the normal and acceptable number for process validation; however, the number of batches should be justified and based on a risk assessment.

1. A written report summarizing recorded results and conclusions shall be prepared, documented and maintained.
2. 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, prospectively for retrospectively.
3. 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.
4. 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.
5. Validation of process shall be based on protocol where The protocol should include or reference at least the following elements:
  - *The manufacturing conditions including operating parameters, processing limits and component (raw material) inputs.*
  - *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.*

## 8.6 Laboratory Documentation

- i. Procedures shall be in place so that the data for all sampling, analysis and calculations are correctly recorded.
- ii. Records duly signed off shall be maintained for all tests and analysis performed in the laboratory.
- iii. Retention of laboratory documents, records and retained samples shall be done for a time period that is consistent with the requirements for the manufacturing records.

## **8.7 Control of Retention Samples**

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

## **8.8 External Laboratory**

- i. There shall be clear defined scope, details of services and responsibilities with contracted external Laboratory.
- ii. External laboratories shall be nationally/ internationally accredited.
- iii. 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.

### III. ESTABLISHMENT - MAINTENANCE AND SANITATION

#### 1. Cleaning and Sanitation

##### 1.1 Cleaning and Sanitation

- i. Cleaning and sanitizing programmes shall be established at facility to ensure that the food-processing equipment and environment are maintained in a hygienic condition to prevent contamination of food, such as from metal shards, flaking plaster, food debris and chemicals and records of the same shall be maintained. The programme should ensure that all parts of the establishment are appropriately clean, and shall include the cleaning of cleaning equipment.
- ii. 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; and*
  - *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 being taken.*
  - *Where ever chances of microbial risk with product air count & swab test being recommended.*
- iii. Cleaning and disinfection chemicals shall be food grade wherever chances of it may come in direct or indirect contact through equipment's or plant surfaces, handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions, and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.
- iv. Cleaning shall remove food residues and dirt and it can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow and vacuum cleaning or other methods that avoid the use of water, and chemical methods using appropriate cleaning agents.
- v. These facilities should be constructed of corrosion resistant materials, be easy to clean and shall have adequate supply of hot and cold potable water, where appropriate. It is recommended to have different colour for hot and cold pipes.

A validation mechanism should be in place for all cleaning programme.

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 (hot water where possible) to remove loosened soil and residues of detergent.
- Dry cleaning or other appropriate methods for removing and collecting residues and debris and
- 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 procedure should be defined for equipment's cleaning.

## 1.2 House keeping

- i. A housekeeping schedule covering manufacturing and storage areas shall be maintained.
- ii. The surrounding areas including roads, parking lots and drains should be well-maintained.
- iii. Walls and floors should be maintained neat and clean. Ceilings and light fixtures should be easy to clean.
- iv. Drains should be sufficiently sized and well sloped. Drains should have removable grates installed for ease of cleaning.
- v. For 3rd party (contract) cleaning companies, the supplier should define clear scope, details of services and responsibilities.
- vi. Waste storage areas should be clearly marked and waste shall be disposed of in a timely manner.

## 2. Maintenance

- I. Maintenance workshops shall be separate and away from production areas. Whenever spares, changed parts and tools are stored in the production area, these shall be kept in dedicated rooms or lockers. Tools and spare parts, for the manufacture of products which are susceptible to microbial contamination, shall be disinfected before these are carried inside the production areas.
- II. Preventive maintenance of equipment and machinery shall be carried out regularly as per the instructions of the manufacturer.
- III. 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.
- IV. Internal & External calibration schedule for critical food safety equipment shall be maintained.
- V. 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.
- VI. Temporary fixes that put product safety at risk shall be removed / permanently fixed in a timely manner.
- VII. 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.

### **3. Pest control System**

#### **3.1 General Requirements**

- i. The organization shall have a nominated pest control technician to manage pest control activities and/or deal with external pest management agency.
- ii. Pest control program shall identify target pests and address plans, methods, schedules and control procedures.
- iii. Program shall include a list of chemicals which are approved for use in specified areas.
- iv. Effective sanitation and Hygiene, inspection of incoming materials and monitoring can minimize pest infestation and thereby limit the need for pesticides.

#### **3.2 Preventing access**

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

#### **3.3 Harbourage and Infestation**

- i. Storage practices shall be designed to minimize the availability of food and water to pests.
- ii. Ingredients and materials shall be stored above the ground and away from walls. Where outside space is used for storage, stored items shall be protected from weather or pest damage (e.g. bird droppings).
- iii. Any Potential pest harbourage such as burrows, undergrowth, old & unused equipments shall be removed.
- iv. Materials found to be infested shall be handled in such a way so as to prevent contamination of other materials or products.

#### **3.4 Monitoring and Detection**

- i. The complete manufacturing plant and surrounding areas must be regularly examined for pest activity
- ii. Pest-monitoring program shall include the placing of detectors and/ or traps in key locations to identify pest activity.
- iii. 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.

#### **3.5 Eradication**

- i. The pest control treatment shall be carried out by trained personnel without posing a threat to the safety or suitability of health supplements/ nutraceuticals.
- ii. The pest control will be carried out 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.
- iii. Pest infestations shall be dealt with immediately by a competent person. The cause should be identified and corrective action taken to prevent reoccurrence.
- iv. In case of insect infestation area, appropriate fumigation should be done as per Plant quarantine Rules.

### 3.6 Pest control – 4 D method

<b><u>1D – Deny Entry- Preventing Entry</u></b>	<b><u>2D – Deny Shelter – Elimination of Harborage of Pests</u></b>	<b><u>3D – Deny Food- Eliminate food sources to pests</u></b>	<b><u>4D – Eradication of Pests</u></b>
<ul style="list-style-type: none"> <li>Seal all holes, crevices at ceilings, walls and floors</li> <li>Threshold clearances of doors &lt; 6mm, fix metal kicking plates</li> <li>Double door / air curtains / strip curtains / mesh screens, self-closing doors at appropriate locations Missing / damaged gratings of drains installed / replaced</li> </ul>	<ul style="list-style-type: none"> <li>Avoid False sealing in processing and storage area</li> <li>Repair defects on walls, floors, ceilings, woodwork &amp; other structures</li> <li>Remove disused / obsolete articles from food premises</li> </ul>	<ul style="list-style-type: none"> <li>Store all foods and condiments in sealed / covered containers</li> <li>Floor free from food remnants</li> <li>Prohibit preparing food and utensils cleaning at other places</li> <li>Store refuse in dedicated closed container and discard periodically to prevent accumulation.</li> <li>Surface channels and gratings clean and clear of food remnants</li> </ul>	<ul style="list-style-type: none"> <li>Clean &amp; disinfect pest infested places, clothing and equipment</li> <li>Use Insectocuter – Place 4.5 to 6 m away from food handling area</li> <li>Use low wall mounted insectocutors</li> <li>Clean insectocutor every week</li> <li>Cover all foods during Pest control treatment</li> <li>Use glue pads inside and rodent boxes outside the processing areas</li> <li>Pest or chemical contaminated food be discarded.</li> </ul>

## 4. Drainage and Waste Disposal

- i. All health supplement/ Nutraceuticals waste and other waste materials shall be removed from time to time from the places where health supplement/ Nutraceuticals is handled, or processed or packed.
- ii. A refuse bin shall be placed in all appropriate places with a proper cover and shall be emptied regularly. The design of the refuse bin shall be such that no hand touch is required. This avoids cross contamination chances. They shall be washed daily with a disinfectant and dried before next use.
- iii. Adequate drainage and waste disposal systems and facilities shall be designed and constructed so that the risk of contaminating health supplement/ Nutraceuticals or potable water supply is avoided.
- iv. Drains shall be designed to meet expected flow 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.
- v. Drains shall be equipped with appropriate traps to effectively capture contaminants.
- vi. Wherever existing, 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.
- vii. Segregation of non-biodegradable waste like plastics /metals / glass materials, bags, containers should be done, before disposal.
- viii. Waste disposal shall be done in accordance with local rules and regulations in a hygienic manner.
- ix. The disposal of sewage and effluents (solid, liquid and gas) shall be as per the Factory/Environment Pollution Control Board requirements.

## **IV. ESTABLISHMENT - PERSONAL HYGIENE AND EMPLOYEE FACILITIES**

### **1. Health Status and Illness & Injury**

- i. 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 infectious and other communicable diseases. A record of these examinations shall be maintained.
- ii. The employees in the health supplement manufacturing premises shall be inoculated against the enteric group of diseases as per recommended schedule of the vaccine and a record shall be maintained.
- iii. Personnel known, or, suspected to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through health supplement, shall be prevented from handling health supplements or materials which come in contact with health supplements.
- iv. Health supplement handlers shall report the following conditions to the management for possible exclusion from health supplement 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 health supplement handler shall be carried out apart from the periodic medical examination, if clinically or epidemiologically indicated.
- v. In health supplement 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.

### **2. Personal Cleanliness**

- i. Health Supplement handlers shall maintain a high degree of personal cleanliness and shall wear work clothing, head covering, and footwear that is fit for purpose, clean and in good condition. Work wear shall provide adequate coverage to ensure that hair, beards, moustaches, perspiration, etc. cannot contaminate the product.
- ii. Where gloves are used for product contact, they shall be clean, food grade (like nitrile etc.) and in good condition.
- iii. Health Supplement/ Nutraceuticals handlers must wear sufficient clean and washable or disposable overclothing (including headgear, nose mask, shoe cover and where appropriate, neck-covering and/or beard snood)
- iv. A policy can be implemented to ensure that visitors and contractors are asked 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.
- v. The provision of clear information to all contractors of any hygiene requirements specific to the manufacturing area in which they will be working,
- vi. The implementation of 'return to work' procedures following illness or foreign holidays, particularly in relation to diseases that may have been contracted while away.

- vii. The implementation of a personal medication procedure to control personal medicines that could be a potential contamination risk to the product,
- viii. Protective clothing mandated for use in manufacturing areas or hygiene purposes shall not be used for any other purposes.
- ix. 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, raw versus cooked or ready-to eat) 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.
- x. Hand washing notices shall be posted at appropriate places.
- xi. Fingernails shall be kept clean without nail polish and trimmed.

### **3. Personal Behaviour**

- i. 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.
- ii. Any behaviour or unhygienic practices which could result in contamination of health supplement shall be prohibited in food processing, distribution, storage and handling areas. This includes smoking, chewing or eating, sneezing or coughing over unprotected food, spitting.
- iii. 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.
- iv. The organization should provide separate lockers/place for personnel working in manufacturing areas to keep their personal belongings, tiffin etc. Food contact tools and equipments shall not be kept in personal lockers.

### **4. Work wear and Grooming**

- i. Personnel who work in, or enter into, areas where exposed products and/or materials 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).
- ii. Clothing mandated for health supplement/ Nutraceuticals protection or hygiene purposes shall not be used for any other purpose.
- iii. Work wear shall not have buttons, outside pockets above waist level.
- iv. Work wear shall be laundered at predefined intervals.
- v. Work wear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.



- vi. Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints,
- vii. Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

## 5. Visitor Control

- i. Organisations should implement and display visitor control policy.
- ii. The Food Business shall ensure that visitors to its food manufacturing, processing or handling areas must wherever appropriate, wear protective clothing, footwear and adhere to the all the personal hygiene provisions required for personnel required in the food business.
- iii. Visitor identity cards provisions should be in place to maintain control on visitor's access into restricted areas.

## **V. ESTABLISHMENT - PRODUCT INFORMATION AND CONSUMER AWARENESS**

### **1. Product information and Labelling**

- i. All packaged food products shall carry a label and requisite information as per provisions of Food Safety and Standards Act, 2006 and Regulations made there under so as to ensure that adequate and accessible information is available to each person in the food chain to enable them to handle, store, process, prepare and display the food products safely and correctly and that the lot or batch can be easily traced and recalled if necessary. This should also include information that identifies food allergens in the product as ingredients or where cross contamination cannot be excluded as per FSS (Packaging & Labelling) Regulations, 2011, if applicable.
- ii. All incoming, in-process and finished products shall be suitably identified for product identification, stage of processing, inspection and test status etc. so as to avoid their inadvertent use. Lot identification shall be done to facilitate traceability, product recall, effective stock rotation etc.

### **2. Consumer Awareness and complaint Handling**

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

## **VI. ESTABLISHMENT - TRAINING AND MANAGEMENT**

### **I. Awareness and Responsibilities**

- i. 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.
- ii. Those handling strong chemicals or potentially hazardous substances shall be trained in safe handling procedures and techniques.

### **2. Training Programmes**

- i. Suitable trainings shall be given to all personnel handling food to enable them to have the required knowledge and skills in GHP and GMP for specific tasks along with personal hygiene requirements commensurate with their work activities, the nature of food, its handling, processing, preparation, packaging, storage, service and distribution.
- ii. These training programmes shall be delivered by qualified and trained personnel.
- iii. Training for each employee can cover the following:
  - Skill Matrix of the employee, Gap analysis for training needs
  - particular tasks relevant to the employee's specific role;
  - general good manufacturing practice;
  - the importance of, and factors involved in, personal hygiene.
- iv. Each new employee should receive training upon employment. This training should be repeated, modified or extended as required.
- v. A Training Program exists for all levels of the organization (i.e. part-time, full-time, temporary staff, management, visitors, contract personnel),
- vi. 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, retained records demonstrate that they possess the necessary qualifications/training/experience.
- vii. Training and qualification records shall be maintained for all personnel with relevant details like: Date, Topic, Name of Instructor, appropriate duration, Employee Signatures.

### **3. Instruction and supervision**

- i. Managers and supervisors of food processes shall have necessary knowledge and skills in food hygiene (GHP and GMP) principles and practices to be able to judge potential risks and take necessary action to remedy deficiencies.
- ii. Periodic assessments of the effectiveness of training, instructions programmes as well as routine supervision and checks should be made to ensure that food hygiene and food safety procedures are being implemented correctly and effectively by all personnel.

#### **4. Refresher Training**

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 health supplements/ Nutraceuticals.

#### **5. Management and Supervision**

- i. Persons engaged in manufacturing, packaging, labelling, or holding, or in performing any quality control operations shall have the education, training, or experience to perform the assigned functions.
- ii. The organisation management shall ensure providing necessary trainings & resources to their employees to develop food safety culture at plant site.
- iii. Employees performing specialized job functions should be certified to a recognized industry standard or governmental organization. Certification records shall be verified.
- iv. Standard operating procedure for GMP systems compliance should be maintained and its compliance shall be verified through records /checklists on routine basis.

## VII ESTABLISHMENT – AUDIT, DOCUMENTATION AND RECORD KEEPING

### 1. Self-inspection

A Health supplement/ Nutraceuticals organisation shall undertake regular self-inspections 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 self-inspection in an independent way. The self-inspection 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. Records shall be maintained of the observations made during the inspection, the actions proposed and taken, the relevant time frames for completion. These records shall be retained for a pre-determined period of time.

### 2. Manufacturing Documentation and 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. Etc.
- 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

- Corrective and preventive actions Self-evaluation results

## **C. SUBCONTRACTING OPERATIONS**

### **1. Terms of Agreement/ Contract**

- i. The contract acceptor shall ensure that the terms of the contract are clearly stated in writing. This shall include a Technical Agreement between the two parties.
- ii. 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.
- iii. 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.

### **2. Technical Agreement**

- i. A technical agreement is a useful method of clearly defining the responsibilities of each party.
- ii. Attention shall especially be given to clarifying the responsibilities of each party in relation to key/critical activities, such as:
- iii. The scope of the instructions given by the Contract Giver to the Contract Acceptor,
  - 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,

- iv. The procedure for notifying the Contract Giver of any abnormality during the contracted process.
- v. Any 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.

## **D. STABILITY PROGRAMME**

- i. The purpose of the stability programme is to monitor the product over its shelf life and to determine that the product remains, and can be expected to remain, within specifications under the labelled storage conditions.
- ii. 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 package.
- iii. This mainly applies to the product in the package in which it is marketed / sold, but consideration shall also be given to the inclusion in the programme of bulk product. For example, when the bulk product is 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. In addition, consideration shall be given to intermediates that are stored and used over prolonged periods. Stability studies on reconstituted product are performed during product development and need not be monitored on an on-going basis. However, when relevant, the stability of reconstituted product can also be monitored.
- iv. The stability programme shall be described in a written protocol and results formalised as a report. The equipment used for the stability programme (stability chambers among others) shall be qualified and appropriately maintained.
- v. The protocol for an stability programme shall extend to the end of the shelf life period and shall include, but not be limited to, the following parameters:
  - Number of batches per strength and different batch sizes, where applicable
  - Relevant physical, chemical, microbiological and biological test methods, stability indicating parameters, where applicable
  - 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

- vi. 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 provided that this is justified and documented in the protocol.
- vii. 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, if relevant, shall be included in the stability program (unless none are produced during that year). Scientific justification has to be provided in the event that the principle of bracketing and matrixing designs is applied.
- viii. A summary of all the data generated, including any interim conclusions on the programme, shall be written and maintained. This summary shall be subjected to periodic review.
- ix. For recommended good practice International guidelines like ICH, WHO, USP etc may be referred to.



## **E. BOTANICALS**

### **1. Origin of Botanicals**

- i. The origin of botanical i.e. Country, Region should be ascertained
- ii. The botanical shall be traceable by a Batch no. / Shipment ID
- iii. There shall be a written confirmation available for the relevant batches/lots to show that cultivation/collection, harvest, storage and processing (as applicable) were in compliance with the basic principles of good agricultural and collection practice, particularly in relation to identification and traceability

### **2. Botanical identification and Characterization**

The name of the botanical shall be ascertained

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

- Whole plant: Underground parts only: Specify Root: Rhizome: Tuber: Bulb:
- Aerial parts only: Specify - Stem: Bark: Leaves: Flower: Fruit: Seed:

The Identification of the unprocessed botanical shall be confirmed by any of the following methods

- Macroscopic examination:
- Microscopic examination:
- Chromatographic/spectroscopic examination:
- Other characteristic assay:
- Physical tests;

The traceability records shall be available from point of plant growth.

### **3. Contaminants and Residues**

#### **3.1 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.

#### **3.2 Microbiological contamination –**

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

- Total Plate Count (Total Viable Count)
- Escherichia coli
- Salmonella spp.
- Enterobacteriaceae

– Total combined Moulds/Yeasts

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

## **4. Botanical extract preparation**

The Form of botanical preparation shall be identified (Extract; Comminuted or powdered herbal substance; Essential oil; Expressed juice; Processed exudate; Others)

Forms of Extract

- The botanical extract shall be identified (standardized extract/ quantified extract/ Other extract).
- The Markers present in the botanical extract/other preparation shall be identified (Active markers/ Analytical markers). In case such standards are not specified, the purity criteria generally accepted by pharmacopoeias, namely, Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, relevant Bureau of Indian Standards Specifications, Quality Standards of Indian Medicinal Plants, Indian Council of Medical Research, British Pharmacopoeia, United States Pharmacopoeia, Food Chemical Codex, Joint Food and Agriculture Organization or World Health Organization Expert Committee on Food Additives or CODEX Alimentarius may be adopted by food Business operators.

# **F. HACCP IMPLEMENTATION**

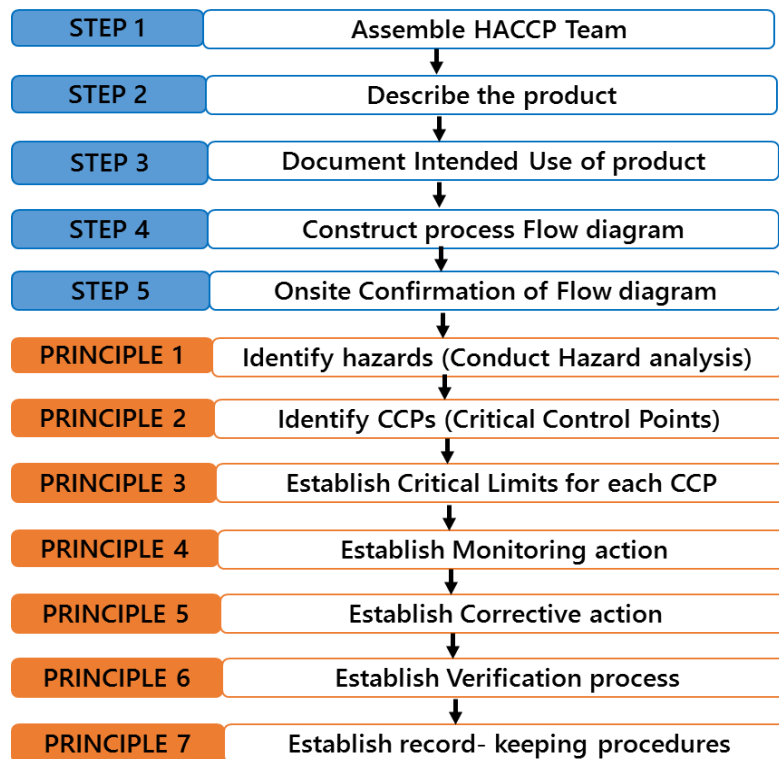
## I. INTRODUCTION TO HACCP

Implementing Hazard Analysis and Critical Control Point (HACCP) is crucial for any food manufacturing 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 must cover start-ups, shutdown and unexpected stoppages during processing.

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. Though HACCP system was designed to aim zero defect products, yet it is not feasible to achieve 100% defect free products. However, it sets a goal to minimize the associated risks during production and subsequently reduce unacceptable unsafe products.

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 HACCP principles.



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 is holds in the processing line.

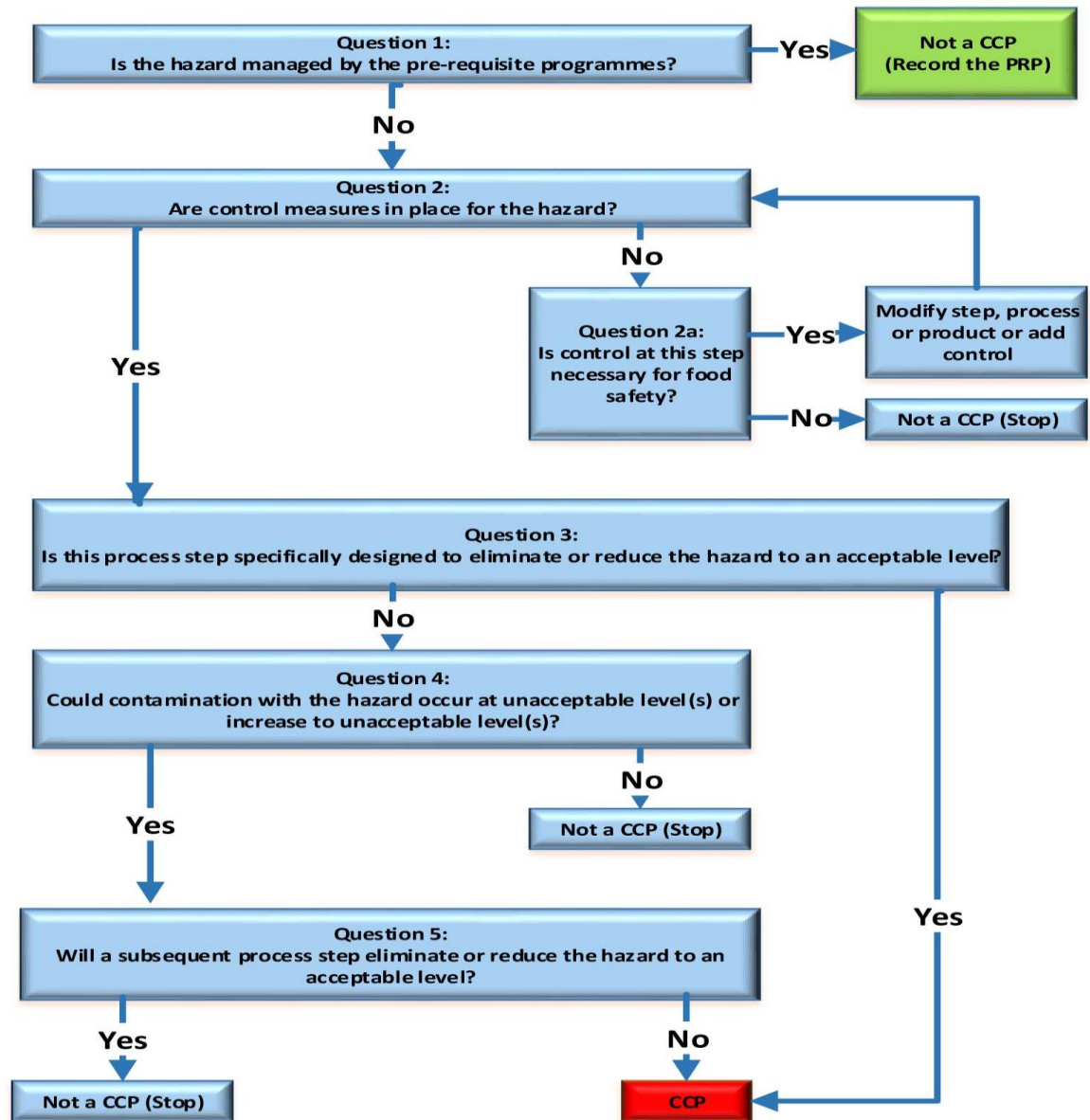
			Consequence/ Severity				
			<u>How severe could the outcome be if the risk event occurs?</u>				
			Severe	Major	Significant	Minor	Insignificant
Probability/ Likelihood	<u>What's the chance of the risk occurring?</u>	Frequent	Extreme	Extreme	Very High	High	Medium
		Likely	Extreme	Very High	High	Medium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

## Introduction to Decision Tree

Hazard Analysis and Critical Control Point (HACCP) decision trees are tools that can be used to help you 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. However, 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 they can be useful in helping you determine whether a particular step is a CCP.

It is vital that you determine the correct CCPs 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.



## II. APPLICATION OF HACCP SYSTEM

### 1. HACCP Implementation steps

#### 1.1 Assemble HACCP team

The food operation shall ensure that the appropriate product specific knowledge and expertise is available for the development and implementation of an effective HACCP plan. A multidisciplinary team shall be assembled either in-house or if such expertise is not available on-site , expert advice shall be obtained from other sources, such as trade and industry associations, independent experts, regulatory authorities, HACCP plan shall be identified and shall describe which segment of the food chain is involved and the general classes of hazards to be addressed (all or selected classes).

## 1.2 Describe 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. Within businesses with multiple product for example, catering operations with similar characteristics or processing steps may be grouped for the purpose of development of the HACCP plan.

## 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.

## 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.

## 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.

## 1.6 List of all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (SEE PRINCIPLE 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. It should then conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is 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 or persistence of foods of toxins, chemicals or physical agents; and
- Conditions leading to the above.

For selection of control measures, consideration shall be given to what control measures, if any, can 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.

### **1.7 Determine Critical Control Points (SEE PRINCIPLE 2)**

For each hazard 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 (see dia 2). The application of a decision tree should be flexible. This example of a decision tree may not be applicable to all situations and alternative approaches may be used.

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.

### **1.8 Establish Critical Limits for each CCP (SEE PRINCIPLE 3)**

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

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

### **1.9 Establish a monitoring system for each CCP (SEE 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:

- a) Measurements or observations that provide results within an adequate time frame;
- b) Monitoring device used;



- c) Applicable calibration method;
- d) Monitoring frequency;
- e) Responsibility and authority related to monitoring and evaluation of monitoring results; and
- f) Records.

All records and documents associated with monitoring CCPs shall be signed by the person(s) doing the monitoring and by the responsible reviewing official(s) of the company.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

### **1.10 Establish corrective actions (SEE 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. This may require identification of the causes of deviation.

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.

### **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 (atleast 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/ relevant staff.

The food business operator shall periodically validate the HACCP plan and necessarily before its implementation and after any changes are made. The objective of the validation process is to ensure that identified hazards are complete, correct and effectively controlled under the HACCP plan. 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.

### **1.12 Establish Documentation and Record Keeping (SEE 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.

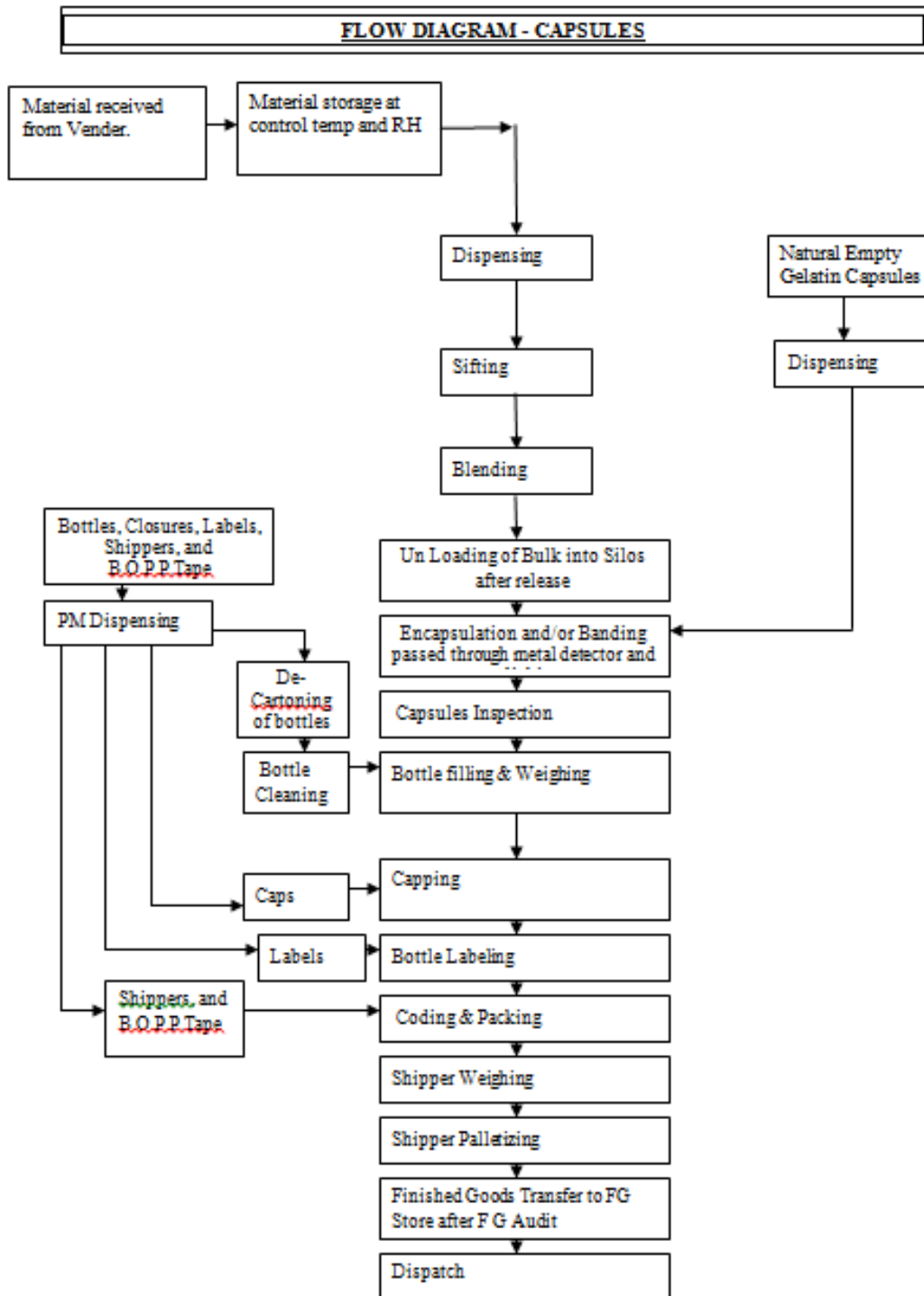
Records to include

- 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.

## 2. HACCP Plan

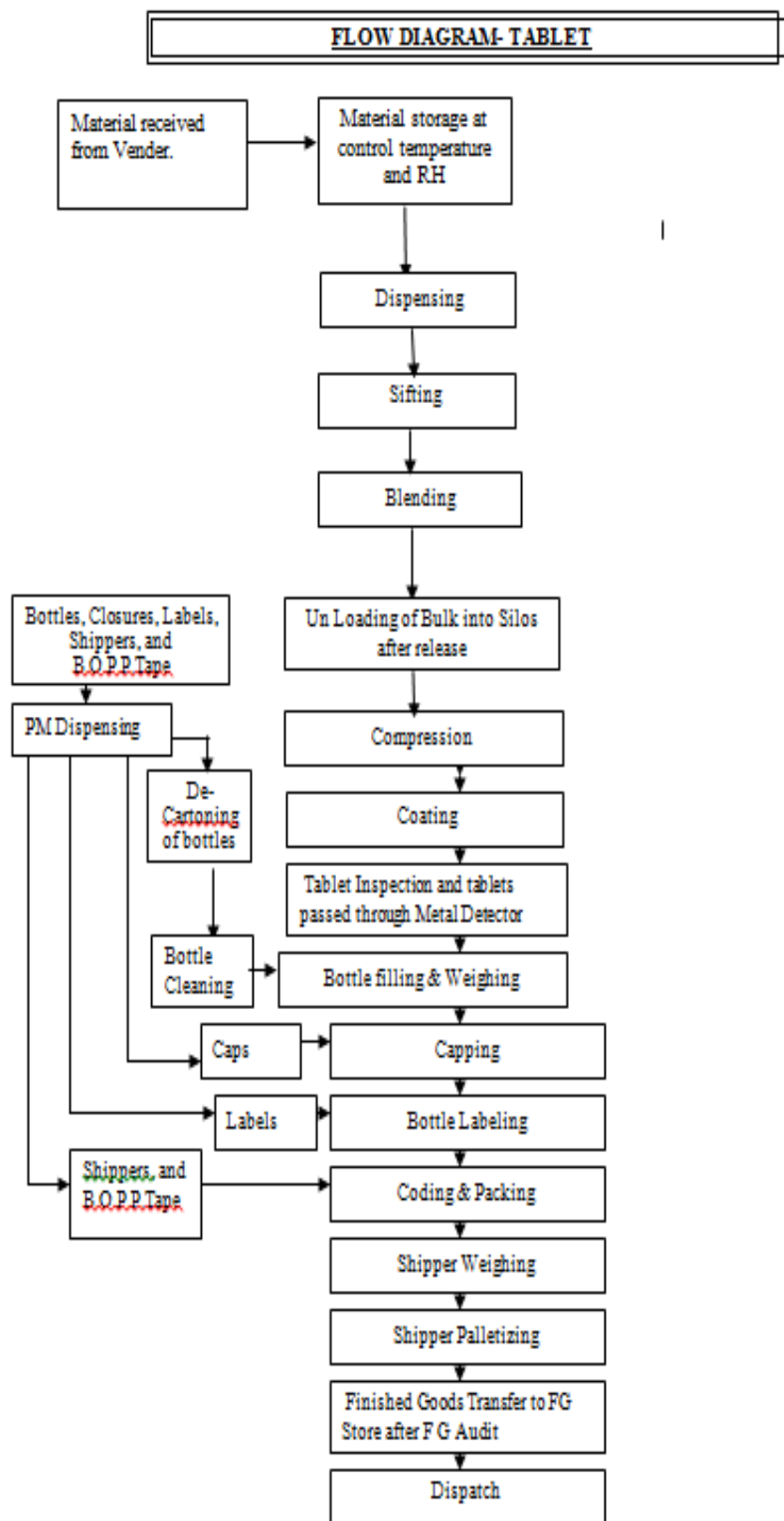
### 2.1 Process Flow Charts

#### 2.1.1 Capsules



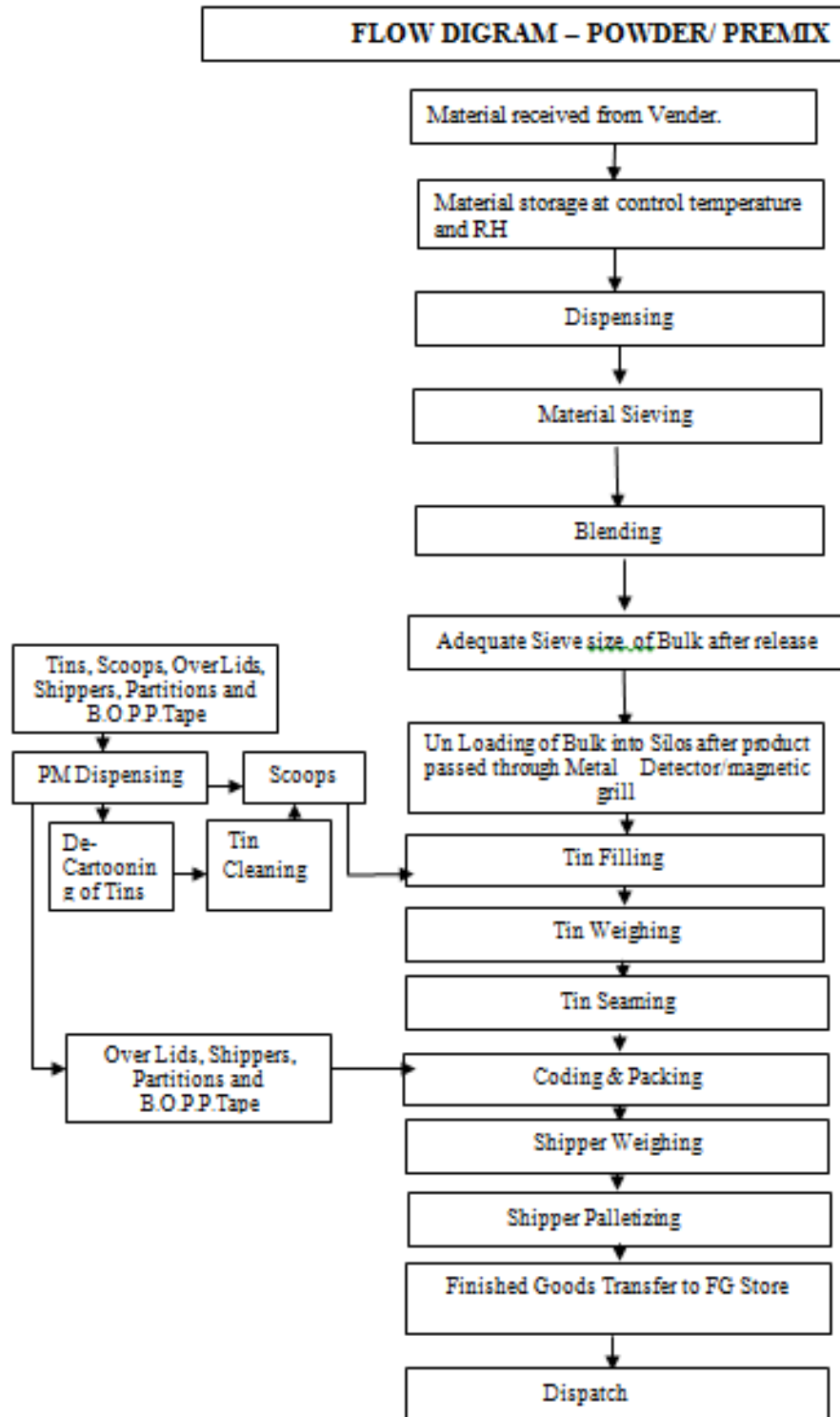
Note: Other forms of packaging of capsules can be strip packaging, blister packaging or alu-alu packaging.

### 2.1.2 Tablets



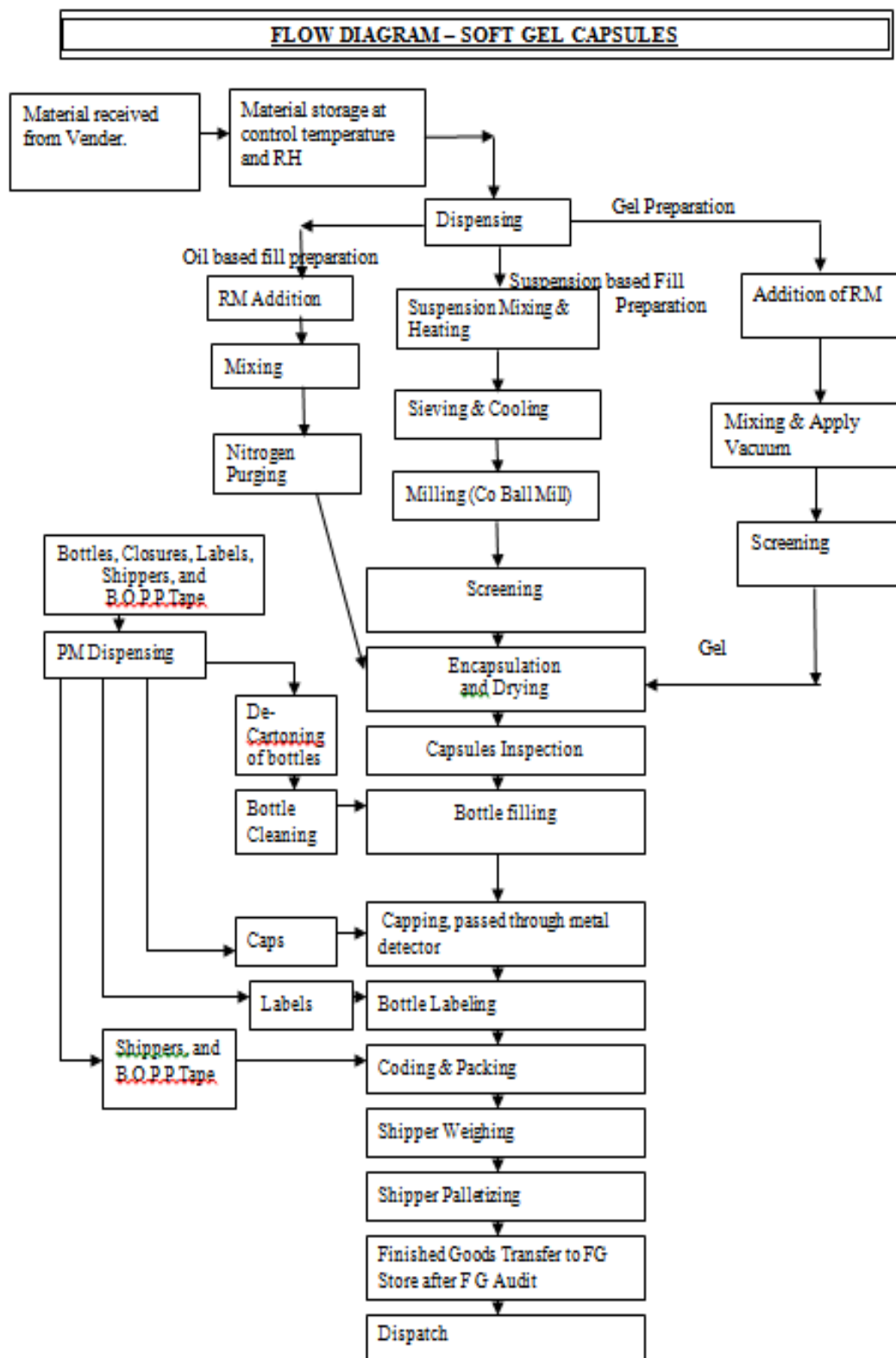
Note: Other forms of packaging of tablets can be strip packaging or blister packaging.

### 2.1.3 Powder/Premix



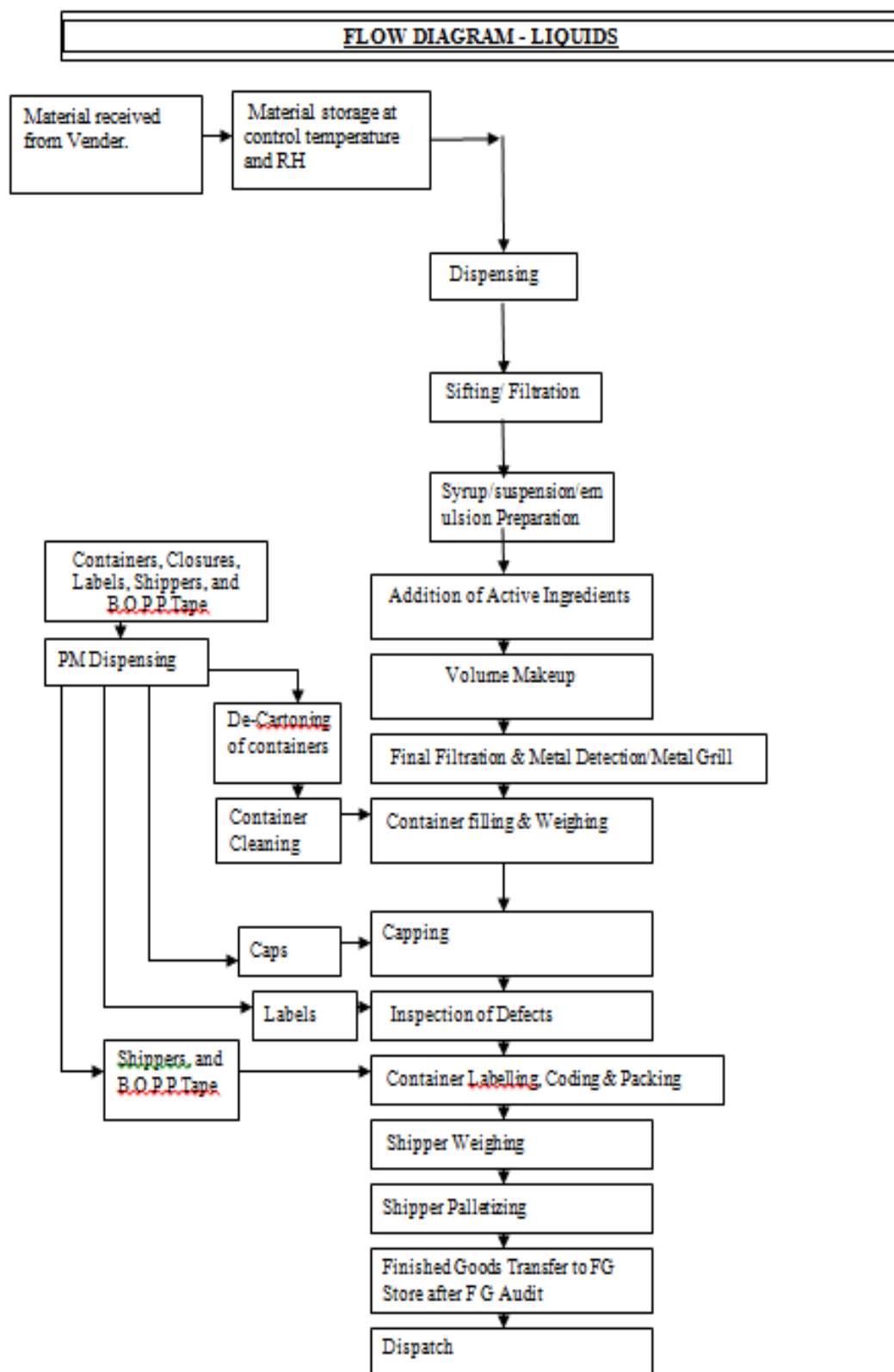
Note: Other forms of packaging for powders could be sachets, pouches, HDPE Containers etc

### 2.1.4 Soft Gel Capsules



Note: Other forms of packaging of soft gel capsules can be strip packaging or blister packaging

## 2.1.5 Liquids



## 2.2 Hazard Analysis

### 2.2.1 Hazard Analysis for Powder

Sr. No.	(1) Ingredient / processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazard require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control Applied at this Step?	
				Yes	No			Yes	No
1.	Receipt of Raw Material	Biological	None	-	-		-	-	-
		Physical	Damaged container	-	No	a) Physical verification is carried out for all incoming material during receipt. b) Material receipt checklist available.	-	-	-
		Chemical	None	-	-	-	-	-	-
2.	Material storage	Biological	None	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-
3.	Weighing and dispensing of raw	Biological	Microbial contamination like <i>Staphylococcus</i>	-	No	a) Environmental conditions are maintained to prevent growth of pathogens. b) Dispensing is carried out	-	-	-



Sr. No.	(1) Ingredient / processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazard require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control Applied at this Step?	
				Yes	No			Yes	No
	materials		<i>aureus, Salmonella</i>			under controlled environment(RLAF). c) Material is being handled by using PPEs. d) Cleaning and sanitation procedure for area and dispensing tools is in place. e) Line clearance procedure followed.			
		Physical	Presence of foreign particles	-	No	a) Material handling by using PPEs. b) Use of RLAF. c) Cleaning and sanitation procedure for area and dispensing tools is in place. d) Dispensing done by trained personnel. e) Line clearance procedure followed	-	-	-
		Chemical	None	-	-	-	-	-	-
4.	Transfer of	Biological	None	-	-	-	-	-	-

Sr. No.	(1) Ingredient / processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazard require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control Applied at this Step?	
				Yes	No			Yes	No
	dispensed material to production	Physical	None	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-
5.	Charging of Material	Biological	Microbial contamination like <i>Staphylococcus aureus</i> , <i>Salmonella</i>	-	No	a) Working in controlled area. b) Personnel hygiene practices followed. c) Material is being handled by using PPEs. d) Cleaning and sanitation procedure for area and equipment is in place.	-	-	-
		Physical	Presence of foreign particles	-	No	a) Material handling by using PPEs b) Personal hygiene practice followed. c) Cleaning and sanitation procedure of equipment and area is in place.	-	-	-
		Chemical	Residue of cleaning agent and previous	-	No	a) Visual check and Line clearance procedure in place. b) Procedure for cleaning	-	-	-

Sr. No.	(1) Ingredient / processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazard require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control Applied at this Step?	
				Yes	No			Yes	No
			product			and sanitation of equipment is in place.			
6.	Blending	Biological	None	-	-	-	-	-	-
		Physical	Pieces of ceramic balls	Yes	-	Ceramic balls may break due to impact of balls on inner surface of ball mill.	Process control: Subsequent sieving step	-	No
		Chemical	None	-	-	-	-	-	-
7.	Sieving	Biological	Microbial contamination like	-	No	a) Working in controlled area. b) Personnel hygiene practices followed.	-	-	-

Sr. No.	(1) Ingredient / processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazard require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control Applied at this Step?	
				Yes	No			Yes	No
			<i>Staphylococcus aureus, Salmonella</i>			c) Material is being handled by using PPEs. d) Cleaning and sanitation procedure for area and equipment is in place. e) Cleaning of sieve and magnetic grill done			
		Physical	Presence of foreign particles	Yes	-	a) Sieving done through #80 mesh	Verification of sieve integrity before and after sieving	Yes CCP-1	-
						b) Magnetic grill attached to sifter.	Verification of magnetic grill before and after sieving	Yes CCP-2	-
		Chemical	Residue of cleaning agent	-	No	a) Visual check and Line clearance procedure in place. b) Procedure for cleaning and sanitation of equipment is in place.	-	-	-

Sr. No.	(1) Ingredient / processing step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazard require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the Preventive Control Applied at this Step?	
				Yes	No			Yes	No
8.	Packaging	Biological	Microbial contamination like <i>Staphylococcus aureus</i> , <i>Salmonella</i>	-	No	a) Working in controlled area. b) Personnel hygiene practices followed. c) Material is being handled by using PPEs. d) Cleaning and sanitation procedure for area and equipment is in place.	-	-	-
		Physical	None	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-
9.	Material storage	Biological	None	-	-	-	-	-	-
		Physical	None	-	-	-	-	-	-
		Chemical	None	-	-	-	-	-	-

## 2.2.2 Hazard Analysis for Liquid

Process step No.	Process step	Hazard			Why it is an hazard	Risk (Likelihood)	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. De-dusting 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

### 2.2.3 HAZARD ANALYSIS OF TABLET

Process step No.	Process step	Hazard			Why it is an hazard	Risk (Likelihood)	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. De-dusting 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

Process step No.	Process step	Hazard			Why it is an hazard	Risk (Likelihood)	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		It can lead to acute and chronic GI	Low	Minor	Personal & equipment hygiene and microbiological verification of sanitation procedures. Use of	No

			as coliform		infections			protective clothing and gloves.	
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

Process step No.	Process step	Hazard			Why it is an hazard	Risk (Likelihood)	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	Due to high RH & environment biological load	It can lead to acute and chronic GI	Low	Minor		

			coliform		infections				
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	-	-	-	-		

Process step No.	Process step	Hazard			Why it is an hazard	Risk (Likelihood)	Severity	Preventive Measures	Is further HACCP study required
		Type	Hazard	Source					
		Chemical	Hazardous chemicals	Residual cleaning chemicals.		Low	Minor		
		Biological	Y&M and pathogens such as coliform	High moisture levels during sifting. Unhygienic and unclean equipment		Low	Minor		
<b>14</b>	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		
<b>15</b>	Shifting of material from R.M.G to	Physical	Foreign matter such as	Un cleaned machine	It can lead to dental & GI	Low	Minor	, Equipment and personal hygiene. Rinse water test after cleaning of equipment.	No

	F.B.D.		dust, glass, metal		injuries				
		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		
		Type	Hazard	Source					
17	Blending for time specified in batch	Physical	Foreign matter such as	Bag bursting, spillage due to	It can lead to dental & GI	Low	Minor	Maintain positive pressure and Proper functioning of AHU class 1 lack clean room environment.	No

	manufacturing record		dust, glass, metal	improper handling	injuries			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.	
		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.	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
	Feed to hopper	Chemical	Presence of previous traces	Uncleaned 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,	Uncalibrated instruments ,	Unpetability	Low	Minor	In process calibrated instruments	No



			weight						
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	-	-		

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	Physical	In proper gross weight	Improper balance calibration.	Improper coating	Low	Minor	Balance calibration .	No
	Weigh the tablets	Chemical	-	-	-	-	-		No
		Biological	-	-	-	-	-		No
22	Coating	Physical	Foreign matter- Dust of previous product	Uncleaned Equipments	Unpetability	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
	Set the parameters for coating	Chemical	Presence of previous traces	Unlearned Equipments	Contaminati on	Low	Minor		-
		Biological	Presence of micro flora	Unlearned Instruments.	It can lead to acute and chronic GI infections	Low	Minor		No
23	Coating	Physical	Checking of thickness, DT, weight	Un calibrated instruments.	Unpetability	Low	Minor	Uncalibrated instruments	No
	In process check	Chemical	-	-	-	-	-		-

		Biological	-	High moisture levels in processing environment.	It can lead to acute and chronic GI infections	Low	Minor		No
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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	Low	Minor		No

					infections				
26	Inspection	Physical	Remove the defective tablets & its record	Improper identification of drums, Improper light	Unpatibility	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

28	Strip Coding	Physical	Undesired coding	Different stereo	Mix up of batches		Minor	Cross checking of each stereo 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 stereo 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 coading of batch number	No verification .	unpatability	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	It can lead to acute and chronic GI	Low	Minor		No

				environment.	infections				
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

35	FG testing by QC	Physical	Checking physical parameter as per specification	Un calibrated parameters.	Unpalatable	Low	Minor	Improper calibrated instruments.	No
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		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	Unidentification	-. Desired material not dispatched	Low	Minor	Check each material with Production dispatch plan and Q.C release certificate.	No
		Chemical	-	-	-	-	-		-
		Biological	-	-	-	Low	Minor		No



## **G. INSPECTION CHECKLIST**

Date		FBO Name	
Food Safety Officer		FBO's representative	
FBO License No.		Address	

Indicate the following – Compliance (C), Non Compliance (NC), Partial Compliance (PC) or Not Applicable (NA)

S. No.	Audit Question	Scoring	
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2	
<b>I</b>	<b>Design &amp; facilities</b>		
2	The design of food premises provides adequate working space; permit maintenance & cleaning to prevent the entry of dirt, dust & pests.	2	
3	The internal structure & fittings are made of non-toxic and impermeable material.	2	
4	Walls, ceilings & doors are free from flaking paint or plaster, condensation & shedding particles.	2	
5	Floors are non-slippery & sloped appropriately.	2	
6	Windows are kept closed & fitted with insect proof screen when opening to an external environment.	2	
7	Doors are close fitted to avoid entry of pests.	2	
8	Equipment and containers are made of non-toxic, impervious, non- corrosive material which is easy to clean & disinfect.	2	
9	Premise has sufficient lighting.	2	
10	Adequate ventilation is provided within the premises.	2	
11	Adequate storage facility for food, packaging materials, chemicals, personnel items etc available.	2	
12	Personnel hygiene facilities are available. (Adequate number of hand washing facilities, toilets, change rooms, rest & refreshment room etc).	2	
13*	<i>Potable water (meeting standards of IS:10500) is used as a product ingredient or in contact with food or food contact surface &amp; tested for quality semi annually. Check for records.</i>	4	
14	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2	
14	Food material is tested either through internal laboratory or through an accredited lab. Check for records.	2	
<b>II</b>	<b>Control of operation</b>		
15	Incoming material procured as per internally laid down specification & from an approved vendors. Check for records (like specifications, name and address of the supplier, batch no., quantity procured etc).	2	
16	Raw materials is inspected at the time of receiving for food safety hazards.	2	
17	Incoming material, semi or final products are stored according to their temperature and humidity requirement, in a hygienic environment. FIFO & FEFO is practised.	2	
18*	<i>Requisite time and temperature is being achieved, maintained, monitored &amp; recorded while manufacturing/processing. Check for records.</i>	4	
19	Food manufactured/processed is packed in a hygienic manner.	2	
20	Packaging materials is food grade & in sound condition.	2	
21	Cleaning chemicals & other hazardous substance are clearly identified & stored separately from food.	2	

22	Transporting vehicle for food use are kept clean and maintained in good repair.	2	
23	Transporting vehicle are capable of meeting requisite temperature (where applicable).	2	
24	Recalled products are held under supervision & destroyed or reprocessed/reworked in a manner to ensure their safety. Check for records.	2	
<b>III</b>	<b>Maintenance &amp; sanitation</b>		
25	Cleaning of equipment, food premises is done as per cleaning schedule & cleaning programme.	2	
26	Preventive maintenance of equipment and machinery are carried out regularly as per the instructions of the manufacturer.	2	
27	Measuring & monitoring devices are calibrated periodically.	2	
28*	<i>Pest control program is available &amp; pest control activities are carried out by trained and experienced personnel. Check for records.</i>	4	
29	No signs of pest activity or infestation in premises (eggs, larvae, faeces etc.)	2	
30	Drains are designed to meet expected flow loads and equipped with traps to capture contaminants.		
31	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2	
32	Disposal of sewage and effluents is done in conformity with standards laid down under Environment Protection Act, 1986.	2	
<b>IV</b>	<b>Personal Hygiene</b>	2	
33	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2	
34	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2	
35*	<i>Food handlers maintain personal cleanliness (clean clothes, trimmed nails &amp; water proof bandage etc) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc).</i>	4	
36	Food handlers equipped with suitable aprons, gloves, headgear, shoe cover etc; wherever necessary.	2	
<b>V</b>	<b>Training &amp; Complaint Handling</b>		
37	Internal / External audit of the system is done periodically. Check for records.	2	
38	Food business has an effective consumer complaints redressal mechanism.	2	
39	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2	
40*	<i>Appropriate documentation &amp; records are available and retained for a period of one year or the shelf-life of the product, whichever is more.</i>	4	

**Total points ...../90**

Asterisk mark (\*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark (\*) questions, will lead to Non-compliance

**Grading –**

<input type="checkbox"/>	A <sup>+</sup>	85-90	Compliance – Exemplar
<input type="checkbox"/>	A	80-84	Compliance/Satisfactory
<input type="checkbox"/>	B	60-79	Needs Improvement
<input type="checkbox"/>	No grade	<60	Non Compliance

## **H. PROFORMAS/TEMPLATES**

# 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.

## 1.2 Form E – Form of Guarantee

### FORM E

#### Form of Guarantee

Date of sale	Nature and quality of article/brand name, if any	Batch No. or Code No.	Quantity	Price
1	2	3	4	5

Invoice No. \_\_\_\_\_

Place: \_\_\_\_\_

From: \_\_\_\_\_

Date: \_\_\_\_\_

To: \_\_\_\_\_

I/We hereby certify that food/foods mentioned in this invoice is/are warranted to be of the nature and quality which it/ these purports/purported to be.

Signature of the

Manufacturer/Distributor/Dealer

Name and address of

Manufacturer/Packer

(in case of packed article)

License No. (wherever applicable)

## 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 address)				
			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 Signature

## 2.3 Incoming Material Inspection

**Includes all type:** Raw materials, Ingredients, Food additives, Processing aids, Packaging materials, Cleaning and sanitation chemicals, etc.

Material Name:	
Supplier Name:	
Identification/Location of Supplier:	
Quantity 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		
Clearance Date		
Authorized Signatory		

## 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

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

## 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*

*Quality Manager*

*Mfg. Manager*

## 2.7 Rework Record

<u>Batch No</u>	<u>Date</u>	<u>Qty</u>	<u>Material</u>	<u>Source</u>	<u>Time</u>	<u>Finished Product</u>

## 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 Signature**

## 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:

Product Name:

Pack Size:

Manufacturing Date:

Manufacturing Time:

Batch/Lot no.:

#### Traceability Details

Investigation Date:

InvestigationTime Start:

InvestigationTime End:

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	Quantity 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

<b>Complaint Number:</b> _____	
<b>Date:</b> _____	<b>Time recorded:</b> _____ <input type="checkbox"/> am <input type="checkbox"/> pm
<b>Quality related:</b> <input type="checkbox"/>	<b>Food safety related:</b> <input type="checkbox"/>
<b><u>Customer Details</u></b>	
Customer Name: _____	
Phone: _____	
Address: _____	City: _____
State/Province: _____	Zip code: _____
Email: _____	
<b><u>Product Consumed</u></b>	
Product name: _____	
Batch Code/Lot no.: _____	
Package size: _____	
Location purchased: _____	
Date of purchase: _____	Date consumed: _____
How was the product stored? _____	
<b><u>Nature of Complaint</u></b>	
Foreign object <input type="checkbox"/>	Off/ Unsatisfactory Flavor <input type="checkbox"/>
Packaging <input type="checkbox"/>	Illness <input type="checkbox"/>
	Allergic <input type="checkbox"/>
	Others <input type="checkbox"/>
<b>How many people consumed?</b> _____	<b>Ages?</b> _____
<b>Symptoms/Additional Problem Information:</b> _____	
<b>Has the Customer</b>	
Seen a Doctor? _____	Gone to Hospital? _____
Spoken to a public health? _____	Contacted Regulatory Agency? _____
<b>Comments &amp; follow up action</b>	
<b>Feedback from client- Status or date finalized</b>	

## 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							

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

