ReC HaN

Resource Centre for Health supplements and Nutraceuticals

Health Supplements and Nutraceuticals

Guidance Document on Good Manufacturing Practices

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fssai FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
Inspiring Trust, Assuring Safe & Nutritious Food
Health and Family Welfare, Government of India

CII Confederation of Indian Industry

IADSA International Alliance of Dietary/ Food Supplement Associations

Acknowledgement

This "**Guidance Document on Good Manufacturing Practices for Health Supplements and Nutraceuticals**" has been prepared by ReCHaN (Resource Centre for Health Supplements and Nutraceuticals). An initiative between IADSA (International Alliance Dietary/Food Supplements Associations), CII (Confederation of Indian Industry). The guidance was developed by a team of technical experts and Industry members from ReCHaN, within the mandate to deliver well-researched and credible content.

Special thanks to FSMS Division, FSSAI for their valuable contribution and thankful to the members of the FSSAI FSMS - Technical Group on Health Supplements and Nutraceuticals for providing their inputs in building this guidance document.

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ReCHaN TEAM

Contents

Preface

This Guidance Document on Good Manufacturing Practices for Health Supplements/ Nutraceuticals is prepared with an intent to provide general guidance to small and medium manufacturers of Health Supplements/ Nutraceuticals and Ingredients to ensure that food safety related aspects are addressed during the manufacturing process.

This guidance document should be read with the Food Safety and Standard Act 2006, Rules and Regulations 2011 in force or as amended from time to time.

It is advised that anyone involved in manufacturing of Health Supplements / Nutraceuticals is trained appropriately to implement the measures and to demonstrate the behaviours mentioned in the document.

It is to be noted that this guidance document does not intend to replace any legal provisions required by law as applicable from time to time. Further, wherever the provision of this document conflicts with Schedule IV of (regulation 2.1.2) of Food Safety Standards (Licensing and Registration of Food Business Operators) Regulations or any other regulations, for that matter, the provision given in the regulations shall prevail.

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Scope

This GMP Guidance Document covers the entire manufacturing process of Health Supplements/ Nutraceuticals in the form of Powders, Tablets, Capsules, Soft Gel Capsules and Liquids starting from procurement of raw materials to despatch of finished product. There are other approved dosage forms like jelly or gels, semi-solids etc. which have not been included as a part of this GMP Guidance document. It deals primarily on Good Manufacturing Practices that can be followed in the processing of Health Supplements / Nutraceuticals.

Guidance to read the document

This document is written with a purpose to guide small and medium Health Supplements / Nutraceuticals manufacturers, both existing and newly established businesses. The document has two main sections.

The first section includes process steps involved in manufacturing of Health supplements/ Nutraceuticals in Tablets, Capsules, Soft Gel Capsules, Powders and Liquids in the form of process flow diagrams.

The second section is the critical part of this document and it contains the guidance on all the aspects of Good Manufacturing Practices for the Health supplements processing. Readers will also find some recommended practices which are currently practiced in large Health supplements and nutraceuticals manufacturing industries. Though this section is in line with the Regulation requirements (Schedule 4 Part II) and have requirements mentioned with 'shall', yet the readers will find some additional guidance mentioned with 'should'. Readers are requested to make sure the difference between 'shall' and 'should' while reading, analysing, and using the document into practice.

Shall: "To be mandatorily implemented; as provided by rules and regulations"

Should: "Strongly advised for food safety operations"

In addition to the above some of the key industry best practices in various sections have been highlighted for better clarity.

The activities/ practices mentioned in the above two sections in a Health Supplement / Nutraceutical manufacturing process may or may not be carried by the same facility. The tablet processing, powder processing, liquid processing and capsule processing may be carried out by different businesses.

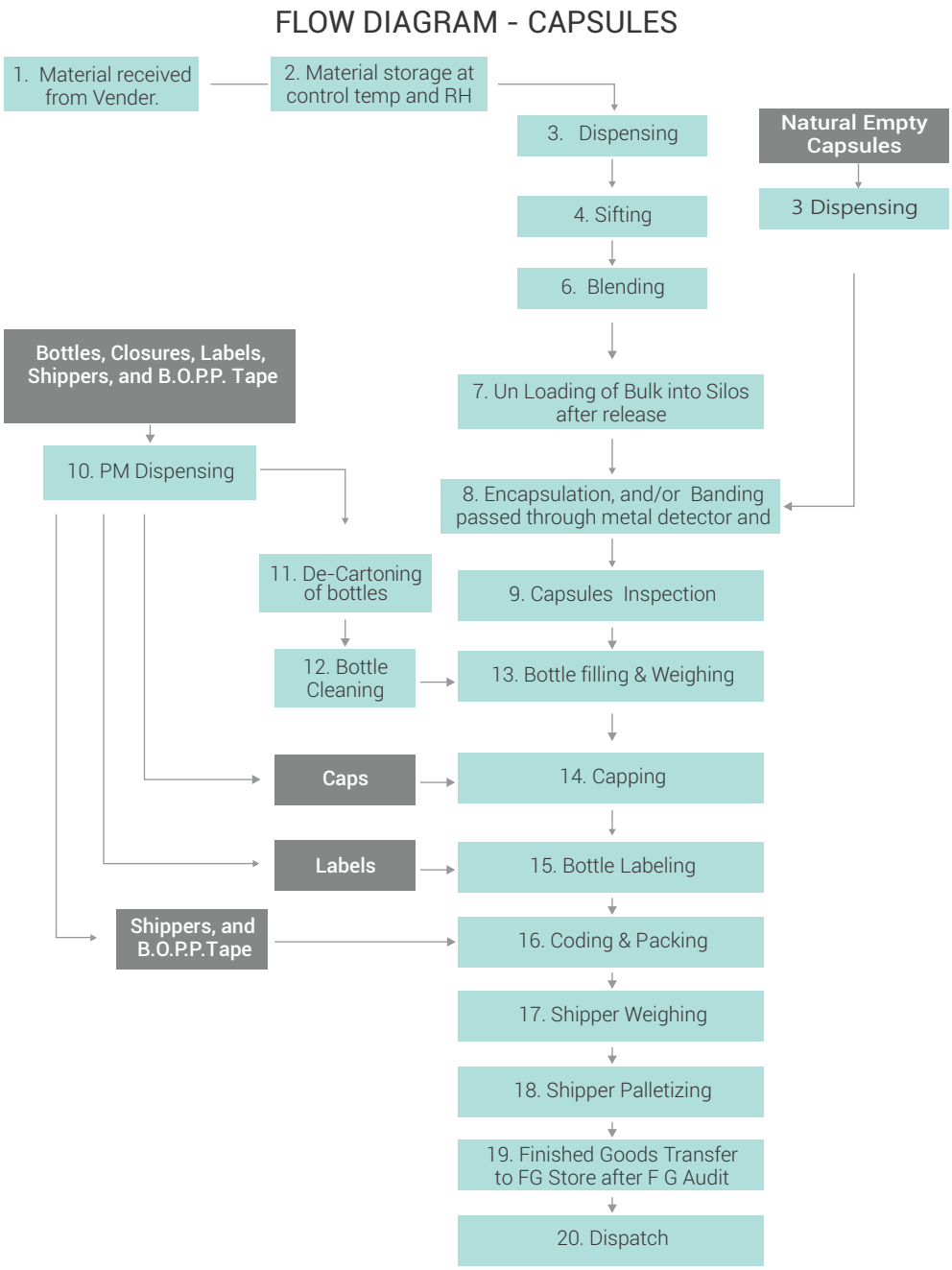
This document is written keeping in mind a Health supplement /nutraceutical facility with the entire range of processes i.e. tablet processing, powder processing, liquid processing and capsule processing.

Section A

Manufacturing Process

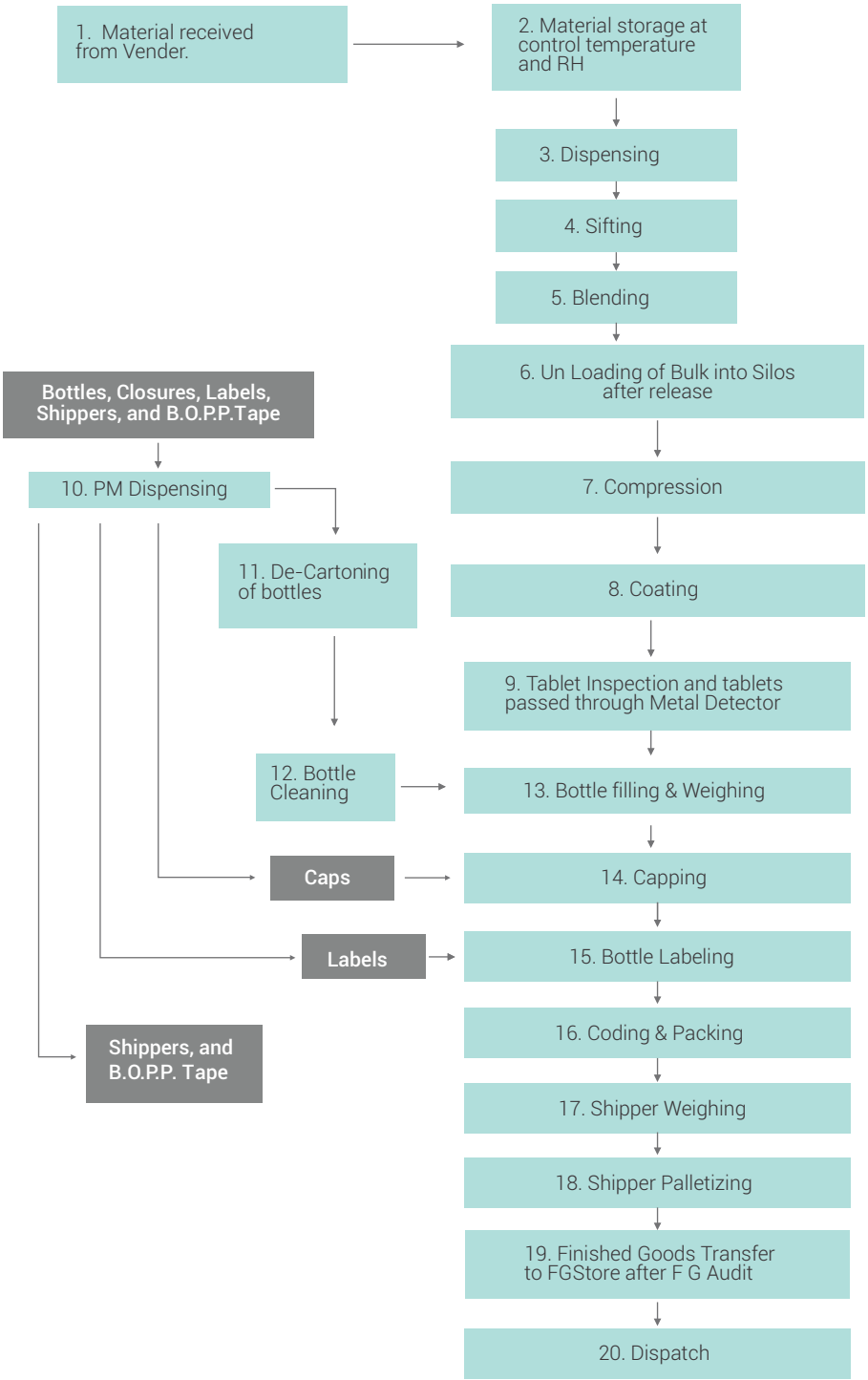
1. Typical Process Flow Diagrams

Find below typical Process Flow diagrams for manufacturing Health Supplements /Nutraceuticals in the form of Capsules, Tablets, Powders, Soft Gel Capsules and Liquids.



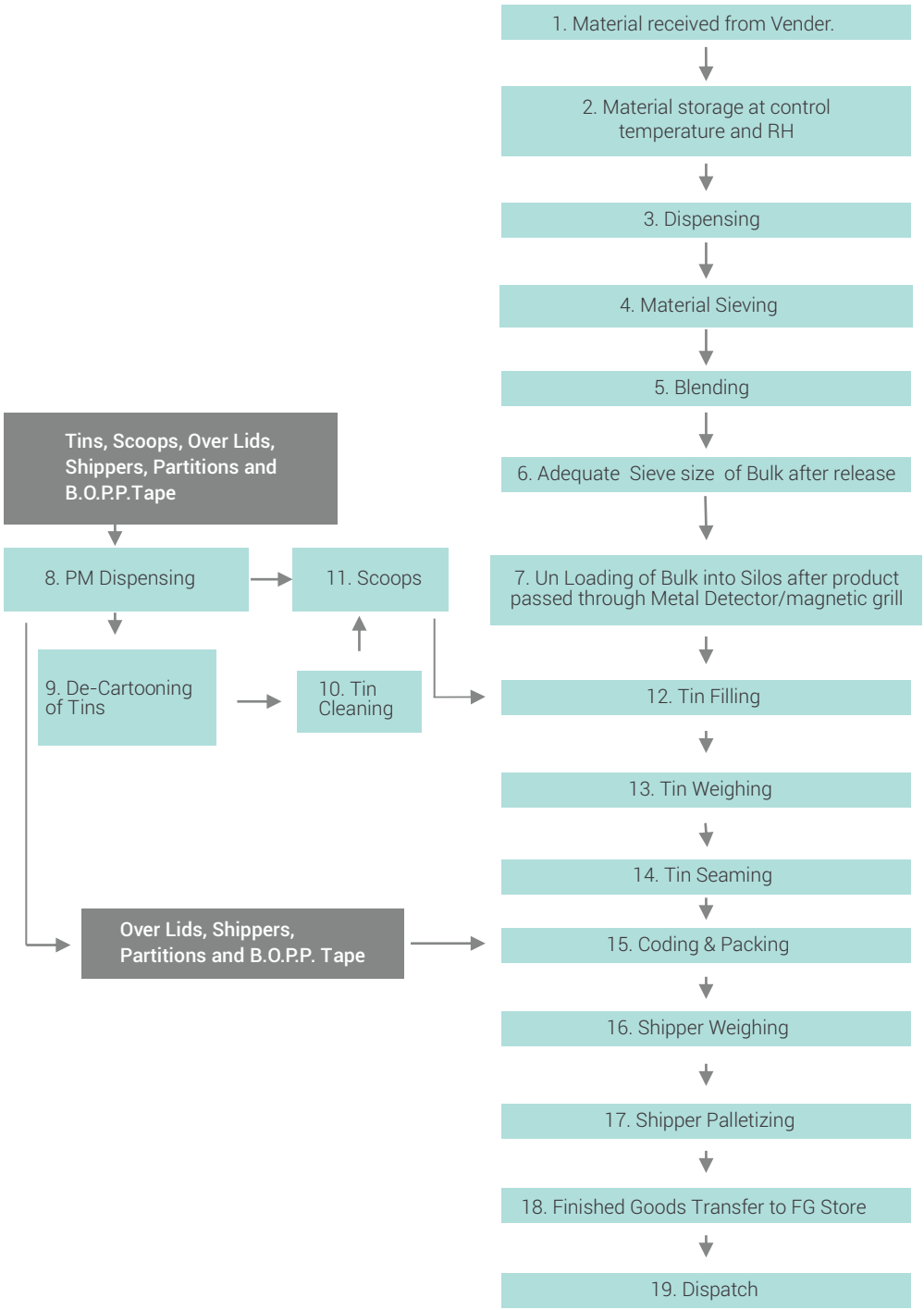
Note: Other forms of packaging of capsules can be strip packaging, blister packaging or alu-alu packaging

FLOW DIAGRAM - TABLET



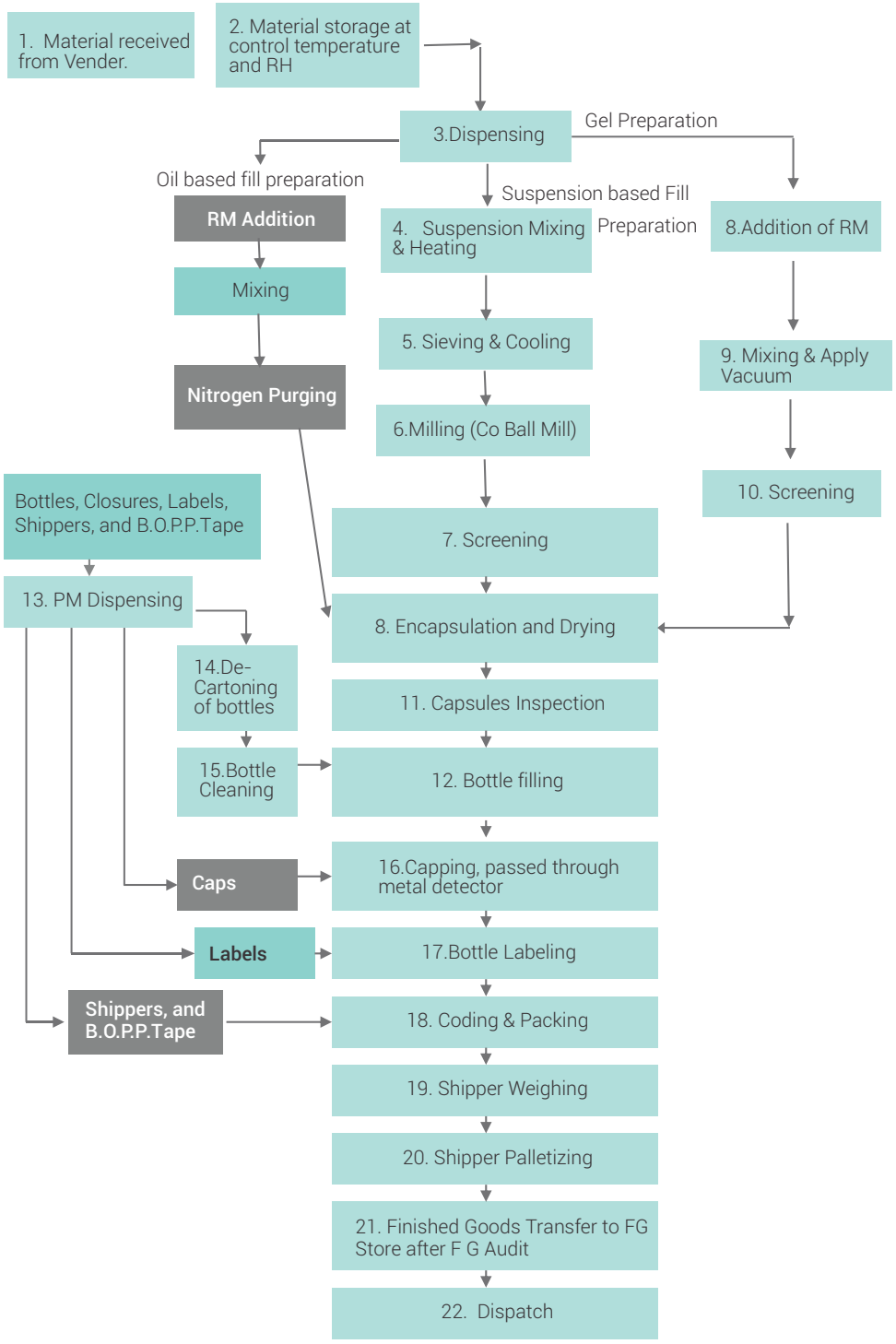
Note: Other forms of packaging of tablets can be strip packaging or blister packaging

FLOW DIGRAM - POWDER / PREMIX



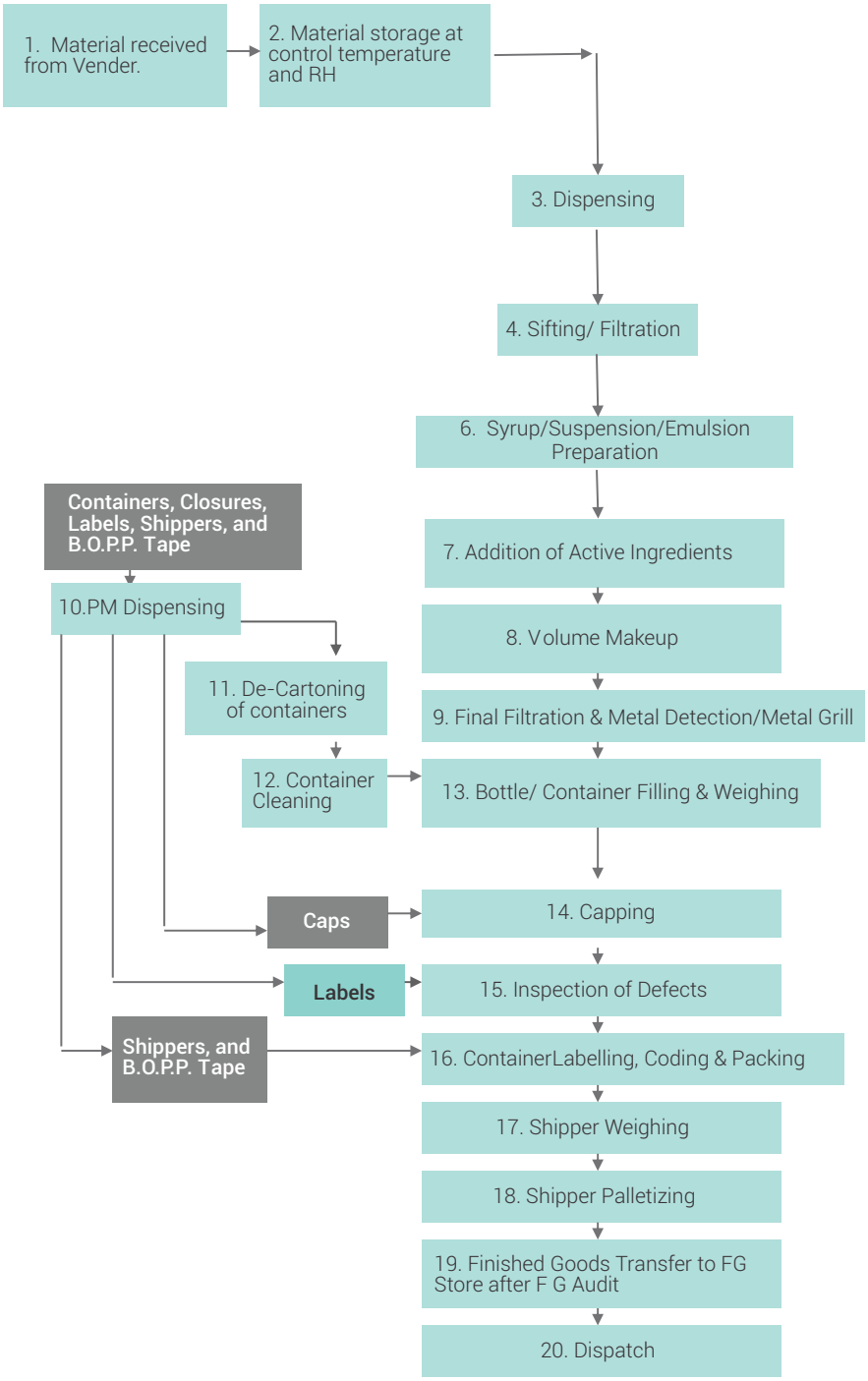
Note: Other forms of packaging for powders could be sachets, pouches, HDPE Containers etc.

FLOW DIAGRAM - SOFT GEL CAPSULES



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

FLOW DIAGRAM - LIQUIDS



2. Material Receipt And Storage

i. Ingredients are received and stored in an enclosed warehouse which has controlled temperature and humidity. The storage condition as recommended by manufacturer or compendium should be followed.

ii. The sampling of the ingredients is done in a sampling booth within the warehouse which has a controlled environment.

Industry best practice for air quality is ISO 8 with RLAF ISO 5 for a dispensing room.

3. Health Supplements/ Nutraceuticals Processing

i. The Health supplement/ Nutraceuticals processing is carried out in an enclosed area which has a controlled environment.

   The industry best practice for air quality and controlled environment in this area is ISO 8, temperature NMT 25 degrees Celsius and RH 60% +/- 5% or as per product manufacturing guidelines if there are some stringent conditions required.

ii. The raw material/ ingredient/ packing material enter the process area through a double door air lock facility which is equipped with air curtains.

iii. Dust control systems are employed during the mixing, sifting, blending, compression and coating operations to avoid any cross contamination.

A Capsule processing

- Dispensing of raw material/ ingredients/ packing material– This is a check to assure the materials entering the manufacturing area for weighing/ quantity check are released as indicated on the batch sheet.
- Sifting/ Sieving is a simple and convenient technique of separating particles of different sizes. It is done to remove any kind of impurity like dust, foreign matter etc.
- Blending is the process of dry mixing of ingredients to get a uniform consistency of nutrients in the mix as claimed by the organisation. Time, temperature and the blending RPM are key parameters that are monitored. Different kind of blenders include Plough blender, Ribbon Blender, Bin Blender, Cone Blender and V Blender.
- The bulk material is checked for quality and then unloaded and transferred into silos.
- The next process is Encapsulation which is to carefully include the powder formulation in the capsule. In case of Liquid formulation ensure Banding after encapsulation.
- The capsules are polished and pass through a metal detector.
- Empty Capsule Sorter or Mini Capsule sorter can be provided to remove the empty capsules / damaged capsules before primary packaging.
- The primary packing material i.e. bottles are cleaned by filtered air.
- The printed capsules are then inspected and filled in bottles followed by capping in a packing machine.
- The filled bottles are then labelled, coded and finally packed in secondary packaging and palletized and transferred to the warehouse.

B Powder/ Premix processing

- After raw material/ ingredients dispensing, sifting and blending operation as explained above, the powder bulk formulation is released after quality testing
- The bulk formulation is again sieved and after passing through metal detector/ maganetic grills the bulk is loaded in Silos.
- The powder/ premix is then filled in primary containers, weighed, capped, coded and then packed in secondary packing material and palletized and transferred to warehouse.

C Tablet processing

- After raw material/ ingredients/ packing material dispensing, sifting and blending operations as explained above, the bulk formulation is unloaded in Silos after quality release.
- Compression is a process of making the tablets by pressing the bulk formulation granules in a die with lower and upper punch. The basic principle behind the tablet compression machine is by hydraulic pressure across the dies. Compression is done in separate cubicles and compression machines are provided with effective dust control systems to avoid cross contamination.
- Tablets are then collected into clean and labelled containers after inspection for the next process of coating.
- Coating is a covering that is applied to the surface of the tablet. Coating is applied using polymers on tablets for organoleptic and protection purposes. Coating pans are supplied with filtered air for drying purposes.
- The coated tablets are then printed with edible grade colours and inspected for quality and passed through metal detector.
- The primary packing material i.e. bottles are cleaned by filtered air.
- The printed tablets are filled in bottles followed by capping, labelling, coding and final packing in secondary packaging, palletized and transferred to the warehouse..

D Soft Gel Capsule processing

- After raw material/ ingredients/ packing material dispensing as explained above there are 2 parallel processes – Fill preparation and Gel Preparation. The fill preparation can be oil based and suspension based.
- In the Gel preparation all the raw material and ingredients are mixed and vacuum is applied across the equipment. The gel is then sieved for any foreign particles and transferred to the Encapsulation machine.
- Suspension based fill preparation – The suspension is first heated and then other ingredients are mixed and heated. The suspension is then sieved, cooled and then milled to get a homogenous suspension and screened and transferred to the Encapsulation machine.
- Oil based Fill preparation – All the raw material and ingredients are added in the oil and mixed. Nitrogen is then purged in the oil to avoid any oxidation and formulation is then transferred to the encapsulation machine.
- In the Encapsulation the formulation is included in the Soft Gel capsule.
- The primary packing material i.e. bottles are cleaned by filtered air.
- The Soft Gel capsules are then inspected, filled in bottles and capped. The filled bottles are then passed through the metal detector.
- The filled bottles are then labelled, coded and finally packed in secondary packaging and palletized and transferred to the warehouse.

E Liquid processing

- After raw material/ ingredients/packing material dispensing and sifting operations as explained above, the syrup/suspension/emulsion etc. Preparation is done in Silos.
- Active ingredients are added to the syrup and volume make up is done to get the final syrup formulation which is then filtered through appropriate seive.
- The primary packing material i.e. bottles are cleaned and inspected.
- The final syrup formulation is then pass through maganetic grill before filling in bottles followed by capping. The filled bottles undergo a final physical inspection.
- The filled bottels are then labelled, coded and finally packed in secondary packaging, palletized and transferred to the warehouse.

4. Finished Goods Storage and Dispatch

i. Finished Good are stored in an enclosed warehouse which has controlledtemperature and humidity. Industry best practice for storage condition is temperature not more than 25 degrees Celsius and Relative Humidity not more that 65% or storage conditions established based on stability studies can be used.

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

iii. The loading of the dispatch vehicle happens through a double door air lock.

iv. Prior to distribution or dispatch of a given batch of a product, it shall be ensured that the batch has been duly tested, approved and released by the quality control personnel. Pre-dispatch inspection shall be performed on each consignment on a random basis to ensure that only the conforming goods are dispatched.

Section B

Pre-Requisite Program

1. Establishment – Design and Facilities

1.1 Location of Establishment

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.

1.2 Building Design, Construction & Layout

1.2.1 Building Design & Layout

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

i. The building shall provide adequate working space with a logical flow of materials,

Building Layout **Courtesy of Amway**

products, personnel and to the extent that is practicable physical separation of raw from processed area to prevent any cross-contamination.

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

iii. 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.

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

1.2.2 Internal Structures

i) Walls and Partitions

- They shall be soundly constructed of materials that are durable, cleanable, impervious to food, grease and water with no toxic effect in intended use. For example: emulsion oil paint (which is easily cleanable by wiping); tiles (which are less porous and causes less crevices).
- Premises shall be free of flaking paint and plaster to prevent the accumulation of dust, minimise condensation, and shredding of particles.
- Wall floor joints should be curved in processing and packaging areas to facilitate cleaning.
- Wall and pillar guards (SS) should be used to avoid daily wear and tear of the surfaces.

ii) Ceilings and overhead fixtures

CEILINGS

- Shall be maintained in sound condition and constructed of materials that are durable, cleanable, 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.

OVERHEAD FIXTURES

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

iii) Floors

- Shall be non-slippery, sloped appropriately, to allow adequate drainage. The drainage shall flow opposite to the flow of manufacturing process flow.
- shall be maintained in good repair with no cracks and crevices
- 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) Doors

- Shall have smooth, non-absorbent surfaces. Wooden doors are not recommended as it promotes mould growth, termites with ageing.
- shall be easy to clean
- Shall be close-fitting and with suitable precautions to prevent entry of pests.
- Gaps if any between the door and the floor should be closed with suitable

material like rubber strips, polyurethane etc. to avoid pest entry.

- 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.

v) External opening windows, roof vents or exhaust fan, where present, shall be adequately screened to avoid any external pest ingress.

vi) 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.

1.3 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.

Equipments made of impervious, corrosion free material
Courtesy of Amway

iv. Manufacturing vessels, pipework, and material handling equipment are well bonded and smooth to prevent material build up and promote sanitary conditions. 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,

v. 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.

vi. 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.

vii. There shall be appropriate facilities for cleaning and disinfecting the food contact equipment and instruments, and wherever possible Clean-In-Place (CIP) should all be adopted.

1.4 Facilities/ Utilities

1.4.1 General

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.

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

i) 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.

1.4.2 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 an ingredients) shall be clearly separated and identified from others. Colour coding of separate pipelines for potable water and non-potable water is recommended.

1.4.3 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) < 60%+/- 5% or as recommended by the supplier
- Material / product contact area – ISO 8; Temperature should not be more than < 25° C and RH < 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 and RH < 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 < 25° C and RH 60+/-5%.
- Other Microbiological Testing Areas – ISO 8; Temperature < 25° C and RH 60+/-5%
- Analytical Laboratory – Temperature < 25° C & RH < 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.

vi) 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.

1.4.4 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,

ii) 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.

iii) It is recommended to have an oil free Compressed air system.

1.4.5 Lighting

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. The intensity (that is, the lux level) should be adequate to the nature of the operation. Recommended lux level for processing areas is atleast 540 LUX, as per USFDA Food Code 2013.

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

1.4.6 Personnel Hygiene Facilities

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. Facility shall have following facilities- hand washing, lavatories, changing facility, rest and refreshment room. Such facility shall be suitable located and designated.

a. Hand washing facilities
   - Facility with hot 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.
   - Where hot and cold water are available, mixing taps should be provided.
   - Hand washing notices shall be posted on walls near hand wash stations.
   - Non- Perfumed liquid soap should be used in dispensers to wash hands as soap bars are a potential source of cross contamination.
   - 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.

b. Hand drying and sanitizing facility
   - Hand drier where installed should be in working condition at all the times during working hours.
   - Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Paper towel rolls should be covered from top at all time to avoid dust and dirt on them.
   - Generally, and preferably, hand driers are considered better than paper towels based on cost efficiency and effectiveness.
   - 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.
   - 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.

c. Lavatories
   - Lavatories shall be separate from other areas and shall not be directly connected to the storage and manufacturing areas. 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.
   - 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.
   - All toilet facilities should be clean and sanitized at all times of the working hours.
   - Toilets should be so designed so as to ensure hygienic removal of waste matter.
   - Toilets should be well lit and ventilated and should not open directly into food handling areas.
   - Lavatories shall be separate from other areas and shall not be directly connected to the storage and manufacturing areas.

d. Changing facilities
   - Suitable and sufficient facilities for persons working in the processing areas should be provided for changing their clothes, keeping their personal belongings and Street footwear.
   - 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).
   - Factory footwear should be cleaned periodically and not to be used fro external purposes.

e. Rest and refreshment room
   - Rest & Refreshment Rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas.
   - Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods.
   - 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.

1.4.7 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 form 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.

1.5 Area Classification for Cleanliness

i) Introduction: movement of material and methods, low to high

iI) 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.

iii) 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 enviornmental conditions in respect to microbial loads.

2. Establishment – Design and facilities

2.1 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.

2.2 Storage and Material Control

2.2.1 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. Materials and product shall be suitably stacked with due regard given to safety.

iii. 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.

2.2.2 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 appropiately.

2.2.3 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. 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.

iii. 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 .

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

2.2.4 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.

2.3 Health Supplement/ Nutraceuticals Processing

2.3.1 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.

2.3.2 Manufacturing Requirements for Tablets/Capsules, Liquids, Powder/ Premixes

A For Manufacture of Dosage Forms (Tablets And Capsules)

1. General

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

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

iii. All raw materials and ingredients shall be tested and released prior to dispensing. Raw material shall be dispensed as per BOM (Bill of Material)

iv. Air conditioning shall be provided wherever necessary to avoid any cross contamination during health supplement processing.

v. 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.

vi. Filters shall be installed in air extraction systems with discharge points to retain dust and protect the factory and local environment.

vii. Material shall be protected against by particles of metal or wood. The use of metal detector is recommended. Wooden equipment should be avoided.

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

ix. All ingredients for a dry product shall be sifted before use unless the quality of the input material can be assured.

x. 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.

xi. The maximum period of storage of the bulk materials shall be validated and specified.

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. 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.

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.
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.

    Industry best practice for environment conditions of this area are Temperature 19-23 Degrees Celsius and RH < 60%+/- 5%-or as per the product requirements.
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.

This section can be shifted to Vendor Management section. Guidance required for edible grade color.

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 the 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. 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 checkwares to check for empty packets and broken tablets.

B For Manufacture Of Liquids

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 used 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.

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. 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.

C FOR MANUFACTURE OF POWDER

1. Building and Equipment

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.

2.3.3 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

2.4 Allergen Management

Allergen handling Major Allergens are –

i. Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;

ii. Crustacean and products of these;

iii. Eggs and egg products;

iv. Fish and fish products;

v. Soybeans and products of these;

vi. Milk and milk products (lactose included);

vii. Peanut, tree nuts and nut products; and

viii. Sulphite in concentrations of 10 mg/kg or more.

Allergen Control and Management 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." 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. 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. 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. 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.

2.5 Health Supplement/ Nutraceuticals Packaging and Warehousing

2.5.1 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.

2.5.2 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. Pallet matrix to be added. (annexure 1)

2.6 Rework & Control of Non-conforming Product

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.

i. 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.

ii. All Traceability records for rework shall be maintained.

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

iv. 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.

v. 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.

vi. Standard operating procedure should be defined and documented for handling any

rework or non-confirming products.

vii. Additional inspection of reworked/reprocessed in-process or finished product is required and documented.

2.7 Transportation and Distribution

Adequate storage and transportation condition requirement shall be in place.

i. 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.
ii. 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.
iii. A procedure should be establish to deal with damage occurring when goods are in storage or distribution,
iv. Security precautions shall be establish for deterring and preventing any tampering with goods in storage and distribution.
v. Any docks, railway sidings, bays, driveways, etc. within the factory complex should be kept free from accumulation of debris and spillage.
vi. Fork lift and other trucks used within the storage areas should normally be battery driven or otherwise equipped to prevent fume or fuel contamination.
vii. The dispatches of finished goods must follow FIFO or FEFO (First Expiry First Out) system.

2.8 Traceability and Recall

2.8.1 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.

2.8.2 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. 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.

2.9 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 though 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.

2.9.1 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

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

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.

2.9.2 Laboratory Personnel

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

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

2.9.3 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.

2.9.4 Sampling

i. Sampling procedures shall be established and documented.

ii. 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

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

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

2.9.5 Analysis

i. Written procedures shall be in place for the preparation of the reagents to be used in the analysis.

ii. 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

iii. Reference standards and any secondary standards prepared from them should be stored, handled and used according to instructions.

iv. Validation shall include the following parameters
   - Specificity / selectivity;
   - Recovery;
   - Precision;
   - Linearity and range;
   - Accuracy;
   - Limit of Detection (LOD) / Limit of Quantitation (LOQ)

v. Validation details shall be recorded and retained. Results of any sample analysis should be within the validated range of the methods used.

vi. 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.

2.9.6 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.

2.9.6.1 Control of Retention Samples

- Retention samples of key raw materials and finished products should be stored in appropriate conditions and quantity.
- Retention samples of finished products shall be stored in the same or simulated containers as per shelf life in which the finished products has been actually marketed.

2.9.7 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.

3. Establishment - Maintenance and Sanitation

3.1 Cleaning and Sanitation

3.1.1 Cleaning and Sanitation

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.:

a. 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.

b. 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.

c. 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.

d. 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.

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

f. 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.

g. Designated area with lock & key provision should be allocated for cleaning equipment's & chemicals.

h. Where ever necessary & applicable CIP procedure should be defined for equipment's cleaning.

3.1.2 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.

3.2 Maintenance

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.

- Preventive maintenance of equipment and machinery shall be carried out regularly as per the instructions of the manufacturer.
- The preventive maintenance programme shall include all devices used to monitor and/or control food safety hazards and cover the maintenance procedure, frequency and identification of the person (and/ or external agency) responsible for maintenance activity.
- Internal & External calibration schedule for critical food safety equipment shall be maintained.
- Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination and post maintenance verification shall be done.
- Temporary fixes that put product safety at risk shall be removed / permanently fixed in a timely manner.
- Lubricants, heat transfer fluids or any other similar material shall be food grade where there is no risk of direct or indirect contact with the product.
- Plant equipment's breakdown records shall be maintained.

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

3.3 Pest Control System

3.3.1 General Requirements

i. The organization shall have a nominated pest control technichian 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.

3.3.2 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.

3.3.3 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.

3.3.4 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.

3.3.5 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 recurrence.

iv. Incase of insect infestation area, appropriate fumigation shoud be done as per Plant quarantine Rules.

3.3.6 Pest control – 4 D method

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

3.4 Drainage and Waste Disposal

a. 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.

b. 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.

c. 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.

d. 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.

e. Drains shall be equipped with appropriate traps to effectively capture contaminants.

f. Wherever existing, refuse stores are to be designed and managed in such a way as to enable them to be kept clean and free form animals and pests.

g. Segregation of non-biodegradable waste like plastics /metals / glass materials, bags, containers should be done, before disposal.

h. Waste disposal shall be done in accordance with local rules and regulations in a hygienic manner.

i. The disposal of sewage and effluents (solid, liquid and gas) shall be as per the Factory/Environment Pollution Control Board requirements.

4. Establishment - Personal Hygiene and Employee Facilities

4.1 Health Status and Illness & Injury

i. Health supplement/ Nutraceutical handlers of the manufacturing facility shall undergo a medical examination by a registered medical practitionerbefore 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.

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

Health check-up **Courtesy of Amway**

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.

4.3 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.

4.4 Work wear and Gowning

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,

4.5 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.

Personalized Female & Male Changing room and Lockers **Courtesy of Amway**

5. Establishment - Product Information and Consumer Awareness

5.1 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.

5.2 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.

6. Establishment - Training and Management

6.1 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.

6.2 Training Programmes

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.

These training programmes shall be delivered by qualified and trained personnel.

i. 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.

ii. Each new employee should receive training upon employment. This training should be repeated, modified or extended as required.

iii. A Training Program exists for all levels of the organization (i.e. part-time, full-time, temporary staff, management, visitors, contract personnel),

iv. 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.

Training and qualification records shall be maintained for all personnel with relevant details like: Date, Topic, Name of Instructor, appropriate duration, Employee Signatures.

6.3 Instruction and supervision

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.

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.

6.4 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.

6.5 Management and Supervision

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.

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

Employees performing specialized job functions should be certified to a recognized industry standard or governmental organization. Certification records shall be verified.

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

In house Training Centre **Courtesy of Amway**

7. Establishment - Audit, Documentation and Record Keeping

7.1 Self-inspection

i. 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.

ii. 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.

iii. 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.

7.2 Manufacturing Documentation and Records

i. The Manufacturing or Batch Records shall be checked at each level and approved by QA

ii. Deviations shall be documented, justified and approved by QA.

iii. Manufacturing or Batch Records shall include the following:

a. Bill of material (BOM), Manufacturing formula, Process flow chart.

b. Manufacturing Instructions, Packaging list, Packaging Instruction, Labels etc.,

c. Documentation for each significant step in the manufacturing process

d. Written procedures for production line start-up, shutdowns and change-overs well defined.

iv. 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

Section 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:

   a. Health supplement/ Nutraceuticals shall be produced safely within the manufacturing environment,

   b. 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,

   c. To agree on levels of sampling of finished products and sample plans to be used in case of dispute,

   d. To agree on the methods for determination of dates of expiration and the confirmatory documents,

   e. To evaluate the adequacy of the control resources, systems, methods and records of the manufacturer,

   f. To agree, wherever possible, objective methods of examination; subjective measurements should conform to recognised and accepted standards impossible,

   g. To agree the period for record keeping.

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

2. Technical Agreement

A technical agreement is a useful method of clearly defining the responsibilities of each party.

i. Attention shall especially be given to clarifying the responsibilities of each party in relation to key/critical activities, such as:

ii. 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,
- The procedure for notifying the Contract Giver of any abnormality during the contracted process.

iii. 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.

Section D

Stability programme

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.

i) 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.

ii) 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.

iii) 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.

iv) 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:
   a) Number of batch(es) per strength and different batch sizes, where applicable
   b) Relevant physical, chemical, microbiological and biological test methods, stability indicating parameters, where applicable
   c) Acceptance criteria
   d) Reference to test methods
   e) Description of the container closure system(s)
   f) Testing intervals (time points)
   g) Description of the conditions of storage
   h) Other applicable parameters specific to the finished product

v) 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.

vi) 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.

vii) 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.

viii) For recommended good practice International guidelines like ICH, WHO,USP etc may be referred to.

Section E

Botanicals

1 Origin of Botanicals

a. The origin of botanical i.e. Country, Region should be ascertained

b. The botanical shall be traceable by a Batch no. / Shipment ID

c. 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

a. The name of the botanical shall be ascertained

b. 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:

c. 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;

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

e. Contaminants and Residues

i. Chemical contamination -

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

ii. 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

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

3. Botanical extract preparation

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

b. Forms of Extract

   i. The botanical extract shall be identified (standardized extract/ quantified extract/ other extract)

   ii. The Markers present in the botanical extract/other preparation shall be identified (Active markers/ Analytical markers) under clause 3 – general requirements – on purity addd as per point 9.

Section F

Annexure – Forms Template

Annexure I

Templates of documents and records required by Health Supplement/ Nutraceuticals manufacturers
Some of the formats have been specified by FSSAI. Other below templates can be used as reference.

LIST OF TEMPLATES

Record No.	Record Title
1.	Medical certificate for Food handlers-FSSAI
2.	Form D1 Annual Return
3.	Non-Conformance Report
4.	Product Recall Record
5.	Product Identification and Traceability
6.	Product Recall – Mock Drill Report
7.	Correction and Corrective Action Report
8.	Customer/Consumer Complaint Log
9.	Training Record
10.	Training Effectiveness Record
11.	Visitor Record
12.	Monitoring of Personal Hygiene
13.	Non-Conforming material/Product
14.	Operation Log Sheet (Template for temperature control)
15.	Equipment Breakdown Maintenance Report
16.	Pest Monitoring record
17.	Approved Supplier List
18.	Incoming Vehicle Inspection Record
19.	List of Monitoring and Measuring Devices and Records of Calibration
20.	Preventive Maintenance Schedule
21.	Preventive Maintenance Record
22.	Product Release Record
23.	Rework Record
24.	Outgoing Vehicle Inspection Record

Templates of Records/ Documents should be available with the manufacturing facility.

Medical Fitness Certificate For Health Supplement Handlers (template)

(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.

Form D1 Annual Return

(For business other than Milk and Milk products)
(See Regulation 2.1.13)

1. Name and address of Licensee: -
2. Address of the authorized premises for the manufacturing / Re-Packing / Re-Labelling of food products:
3. License No. .....
4. Statement showing quantities of food products manufactured/handled/imported and exported in Tonnes

Name of the food product manufactured/handled/ imported/exported.	Size of can / bottle/ any other package (like PP) or bulk package	Quantity in MT	Sale price per Kg or per unit of packing	Value	Quantity exported/ imported in Kg
1.	2.	3.	4.	5.	6.

7.	8.	9.	10.
Name of the country or port of Export	Rate per Kg or per unit of packing C.I.F. /F.O.B.	Value	Remarks

Non- conformance report (Template)

Name of Manufacturing plant:
Date of Internal Audit:
Process Area Audited:
Auditor(s) :
Auditee(s):

Area Covered:

S.No.	Observation Area	Compliance checkpoint	Status (Yes/ No)	Non-Compliance details (if any in this area)	Corrective action planned	Responsibility	Target date of completion	Actual completed on

Product Recall record (Template)

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

Product Identification and Traceability (Template)

Traceability Detail Format
Product Description
Plant Name:
Product Name:
Pack Size:

Manufacturing Date:
Manufacturing Time:
Batch / Lot no:

Traceability Details
Investigation Date:
Investigation Time Start:

Investigation Time 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 Manufacturing	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

Product Recall- Mock Drill report (Template)

Date of Drill:
Starting time of Drills:
Closing Time of Drills:
Overall Time taken:
Product name:
Area Covered:
Mode of Communication used (Telephone / Fax / e-mail):

Persons / Parties contacted:

S.No.	Service point	Location	Name of person contacted	Telephone / Fax / e-mail	Quantity of product lying in stock

Result of physicals verification:
Remarks:

Correction and Corrective Action report

Processing Area:
Date:
Inspected / Audited By:
Processing area incharge:

Non-conformance Observed	
Root cause analysis	
Correction proposed	**Corrective Action Proposed**
Target Date:	Target Date:
Corrective Review	**Corrective Action Review**
Date: Dept Incharge	Date: Dept Incharge

Customer/ Consumer Complaint Log (Template)

Complaint Number: _____

Date: _____ **Time recorded:** _____ ☐ **am** ☐ **pm**

Quality related: ☐ **Food safety related:** ☐

Customer Details

Customer Name: _____

Phone: _____

Address: _____ City: _____

State/Province: _____ Zip code: _____

Email: _____

Product Consumed

Product name: _____

Batch Code/Lot no.: _____

Package size: _____

Location purchased: _____

Date of purchase: _____ Date consumed: _____

How was the product stored? _____

Nature of Complaint

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

How many people consumed? _____ **Ages?** _____

Symptoms/Additional Problem information _____

Has the Customer

Seen a Doctor? Gone to Hospital?

Spoken to a public health? Contacted Regulatory Agency?

_____

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

Training Record (Template)

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				

Training Effectiveness record (Template)

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

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

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

Visitor Record

Date of visit:	
Time of entry:	
Time of exit:	
Name of visitor:	
From (location):	
Whom to meet:	
Purpose of visit:	
Type of visitor:	Please Tick: Type I (Critical areas: Internal processing areas) Type II (Outside processing areas) Type III (Office areas)
Any Allergy/ Infectious disease declaration:	
Belongings description:	
Signature of visitor:	
Signature of Security in-charge:	
Signature of person visited:	

NB: Pls adhere to all the food safety and quality ; and company policies and rules during your visit

Monitoring of Personnel hygiene (Template)

Date:

S.No.	Employee Code	Employee name	Area of work	Hand wash, sanitize (and Gloves where necessary)	Clean & trimmed Nails	No open Wounds	No Covered Jewellery 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														

Non-conforming Material/Product (Template)

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

Operation Log Sheet (Template for Temperature Control)

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

Equipment Breakdown Maintenance report (Template)

Date: **Period of Report:**

S.No.	Name / Code No. of the Machine / Equipment	Location	Nature of Breakdown	Details of repairs carried out	Breakdown Period	Work Done by	Remarks

Pest Monitoring record (Template)

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

Approved Supplier List (Template)

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

Incoming Vehicle Inspection Record (Template)

Date of Incoming Vehicle:
Material in Vehicle received:

Vehicle Type:
Number of Persons accompanying Driver:

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

List of Monitoring and Measuring Devices and Records of Calibration (Template)

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

Preventive Maintenance Schedule (Template)

LIST OF MACHINERY AND EQUIPMENT FOR MAINTENANCE

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	

Preventive Maintenance Record (Template)

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

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

Product Release Record (Template)

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

Rework Record (Template)

Batch No	Date	Qty	Material	Source	Time	Finished Product

Outgoing Vehicle Inspection Record (Template)

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

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

Section G

References

1) IADSA Global Guide to Good Manufacturing Practices on Health Supplements, June 2011

2) General requirements on hygiene and sanitation; Schedule 4; Part II; Food Safety and Standards (Licensing and Registration of Food Business), Regulations 2011.

3) 21 CFR Part 111

4) International Standard ISO 8573-1, Third Edition, 2010-04-15 – Compressed Air

5) International Standard ISO 14644-1/2:2015 – Cleanroom classification and monitoring guidelines

6) General Principles of Food Hygiene CAC/RCP 1-1969

7) ISO 22000:2005

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