FSMS Guidance Documents
On Milk Products
(GHEE)

Version 01: November 2016
CHIFSS (CII-HUL Initiative on Food Safety Sciences)

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Records/ Documents should be available with the manufacturing facility.

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1. **Mother Dairy**
2. **Amul India**

I. Definitions

To provide guidance to users on the interpretation of the key terms used in this document:
Must/Shall: "To be implemented immediately, compulsory, mandatory"
Should: "Strongly advised for current operations and may become mandatory in the future"

(a) Act: The Food Safety and Standards Act, 2006

(b) Adulterant: Any material which is or could be employed for making the food unsafe or sub-standard or mis-branded or containing extraneous matter

(c) Best before: the date which signifies the end of the period under any stated storage conditions during which the product shall remain fully marketable and shall retain any specific qualities for which tacit or express claims have been made. Beyond that date, the food may still be perfectly safe to consume, however, its quality may have diminished. However, the food shall not be sold if at any stage the product becomes unsafe.

(d) Consumer: persons and families purchasing and receiving food in order to meet their personal needs

(e) Date of Manufacture: the date on which the food becomes the product as described.

(f) Date of Packaging: the date on which the food is placed in the immediate container in which it will be ultimately sold

(g) Food: any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances, provided that the Central Government may declare, by notification in the Official Gazette, any other article as food for the purposes of this Act having regards to its use, nature, substance or quality

(h) Food additive: any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities

(i) Food business: any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import an includes food services, catering services, sale of food or food ingredients

(j) Food business operator: a person by whom the business is carried on or owned and is responsible for ensuring the compliance of this Act, rules and regulations made there-under

(k) Food safety: assurance that food is acceptable for human consumption according to its intended use

(l) Food Safety Management System: the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business.

(m) Hazard: a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

(n) **Ingredient:** any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form.

(o) **Label:** any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert

(p) **Lot number" or "code number" or "batch number"** the number either in numerical or alphabets or in combination thereof, representing the lot number or code number or batch number, being preceded by the words "Lot No" or "Lot" or "code number" or "Code" or Batch No" or "Batch" or any other distinguishing prefix by which the food can be traced in manufacture and identified in distribution.

(q) **Manufacture:** a process or adoption or any treatment for conversion of ingredients into an article of food, which includes any sub-process, incidental or ancillary to the manufacture of an article of food.

(r) **Manufacturer- FSSA:** a person engaged in the business of manufacturing any article of food for sale and includes any person who obtains such article from another person and packs and labels it for sale or only labels it for such purposes.

(s) **Package:** a pre-packed box, bottle, casket, tin, barrel, case, pouch, receptacle, sack, bag, wrapper or such other things in which an article of food is packed.

(t) **Risk:** in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard.

(u) **Unsafe**: an article of food which is injurious to health:

i) By the article itself, or its package thereof, or

ii) Consists wholly or in part, any filthy, putrid, rotten, decomposed or diseased animal substance or vegetable substance; or

iii) Is processed unhygienically or the article of food has harmful substance in it or is infected or infested with worms, weevils or insects; or

iv) Has been substituted by inferior or cheaper substance whether wholly or in part; or

v) uses a substance directly or as an ingredient or as additive which is not allowed under the law; or

vi) By virtue of its being prepared, packed or kept under unsanitary conditions; or

vii) By virtue of its being misbranded or sub-standard or food containing extraneous matter; or

viii) By virtue of containing pesticides and other contaminants in excess of quantities specified by regulations.

II. Abbreviations

i) GMP: Good Manufacturing Practices

ii) GHP: Good Hygiene Practices

iii) HACCP: Hazard Analysis Critical Control Point

iv) ACP: Allergen Control Plan

III. Manufacturing/ Processing Parameters

1. **GHEE :** Ghee is prepared by simmering butter, which is churned from cream, and removing the liquid residue. The texture, colour, and taste of ghee depend on the quality of the butter, source of the milk used in the process and the duration of the boiling.

1.1 Manufacturing/ Processing Parameters

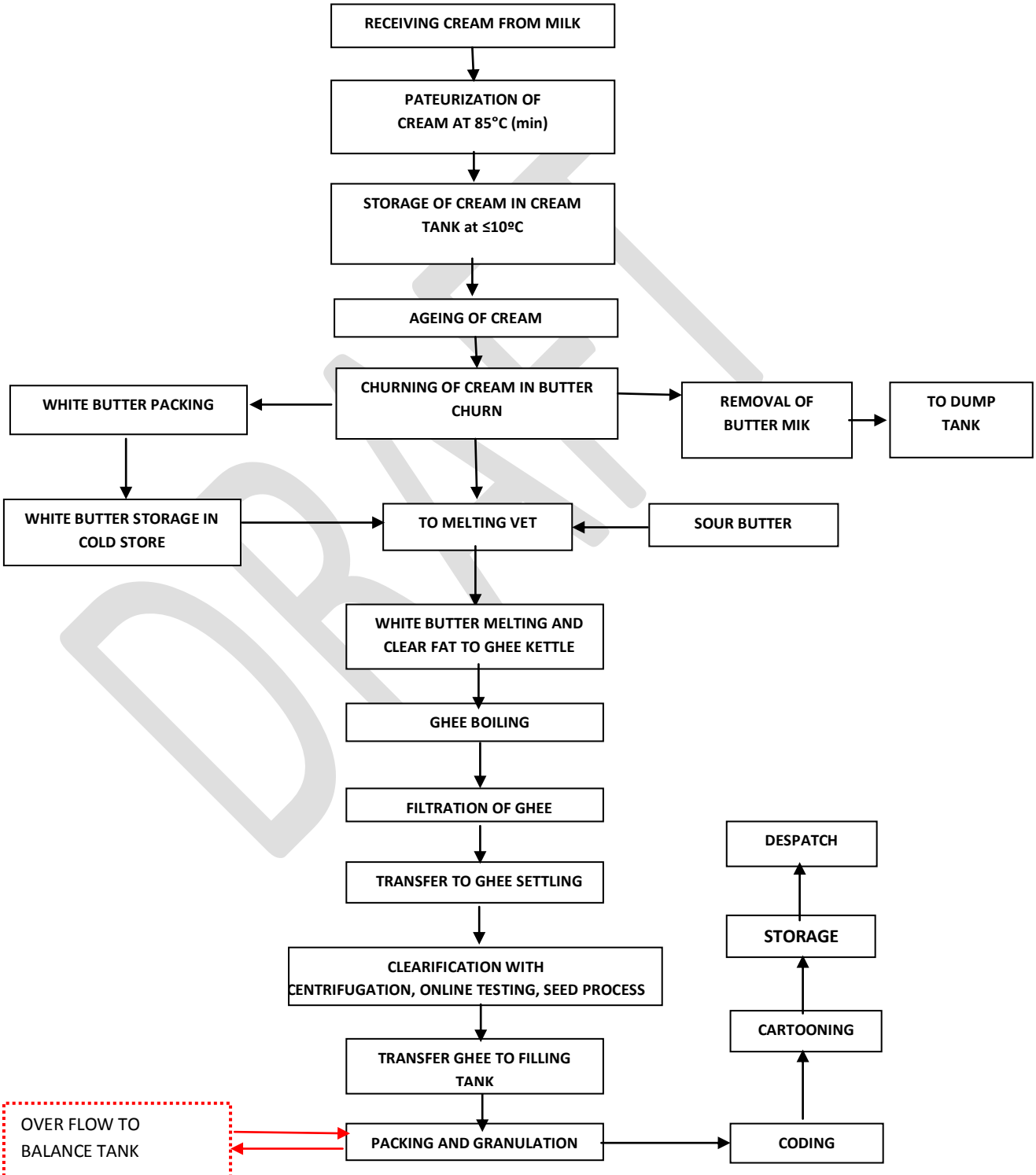

Figure 1: General Ghee Manufacturing Flow chart

1.2 Loading/ Unloading, Warehousing, Transportation, Retail Precautions related to Food Safety & Quality

IV. Pre- Requisite Programs for Food Safety

2 Location and Surroundings

2.1 **Environment:**

a) All the potential sources of contamination should be taken into consideration from the local environment before choosing a location.

b) Food Establishment should be located away from environmentally polluted areas and industrial activities which produce disagreeable or obnoxious odour, fumes, excessive soot, dust, smoke, chemical or biological emissions and pollutants; where potentially harmful substances could enter the product, and which pose a serious threat of contaminating food; areas subject to flooding; areas prone to infestations of pests; and areas where wastes, either solid or liquid, cannot be removed effectively.

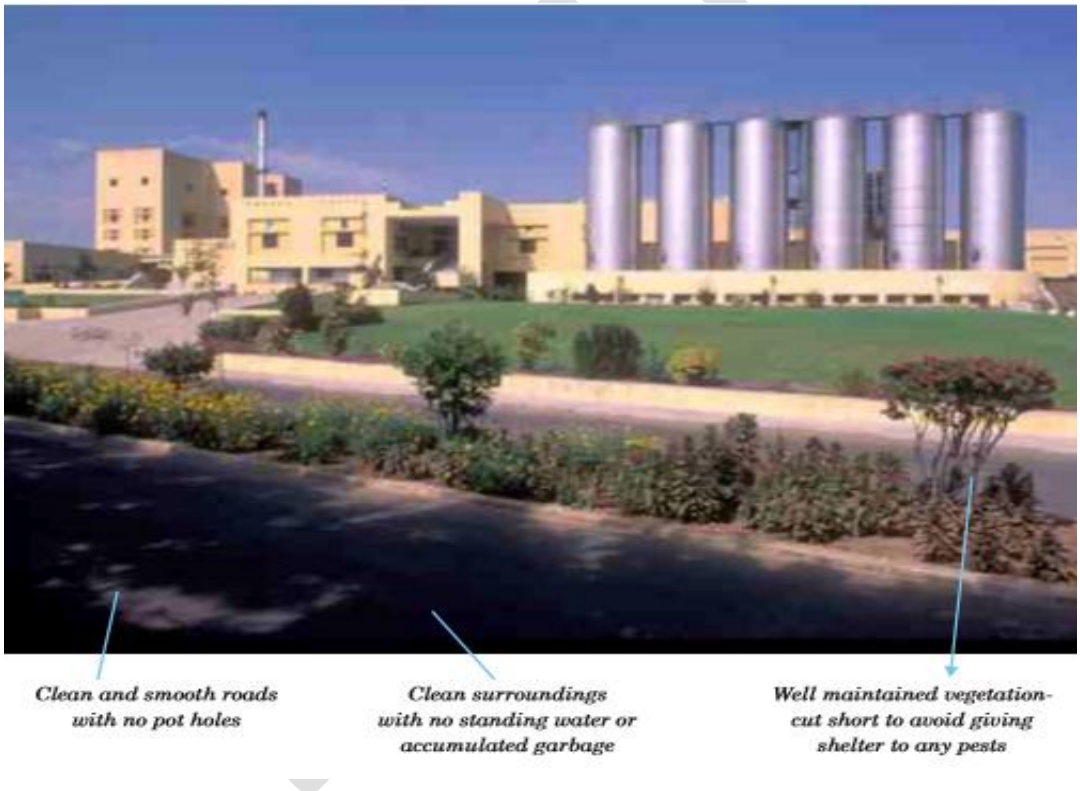

Figure: Outer area conditions

2.2 **Location of establishments:**

a) Site boundaries shall be clearly defined.

b) Site shall be maintained in good order; garden or vegetation, if any, should be tendered or removed and if possible no vegetation should be present near manufacturing areas. This is to avoid any pest or insect harbourage or provide their breeding place.

c) Roads, yards, parking areas should be cleaned daily. Any water accumulation should be avoided through proper drainage system.

2.3 **Building Standard:**

a) Building shall be constructed with materials which does not cause any water seepage or any other ingression of unwanted materials. The building should be structurally sound.

b) Building and overhead structures shall be well maintained.

2.4 **Premises**:

A premises include all the elements of building and building surroundings.

a) Buildings shall be designed, constructed and maintained in a manner appropriate to the nature of the processing operations to be carried out, the food safety hazards associated with those operations and the potential sources of contamination from the plant environments.
Proper care should be taken to minimize or remove the food safety hazards due to any external sources.

b) Building shall be constructed with durable materials and which does not cause any water seepage or any other ingression of unwanted materials. The building should be structurally sound.

c) Building and overhead structures shall be well maintained.

d) Buildings should be so constructed, as to minimize the potential pest entry and harbourage.

e) Local pest issues/threats should be taken into consideration in designing/refurbishing buildings for food manufacturing.

f) The construction of all the ceilings, floors, walls should be such as cleaning inspection and pest treatment can be done easily.

g) All internal building surfaces in material handling, manufacturing and packing areas should be suitable, non-toxic, odor free, easily cleanable and impervious.

h) The use of wood in manufacturing, packing and storage areas should be avoided. Generally wooden pallets are being used. In case wooden pallets are used, proper care should be taken to regularly inspect for its cleaning, maintenance and repair.
Best Practice: Plastic pallets/racks can be used to replace wooden pallets.

3 Layout of Premises and Workplaces

3.1 **Internal design, layout and traffic patterns:**

a) The building shall have sufficient working and storage space to allow all operations to be carried out under hygienic condition.

b) There should be a physical separation of raw from processed areas. This also applies where there is high and low risk areas. Both high and low risk areas shall be separated.
Examples of physical separation may include walls, barriers, or partitions, or sufficient distance to minimize risk.

c) Process flow from receiving to shipping shall be designed to prevent cross contamination. The flow of the entire process should be in one- direction and should not be backwards in any point of processing.

d) Openings intended for transfer of materials shall be designed to minimize the entry of foreign matter and pests.
Recommended: Fly catchers (insectocutors) are installed at the entry of all doors openings. The location of which should be towards outside of the premises so that all flies/ insects are caught even before entry through the door.

Best Practice: Strip sheets made of acrylic are hanged

e) Separate entry for personnels, raw material, finished goods and removal of waste should be defined; to avoid food cross-contamination.

3.2 **Walls**:

a) The wall/floor junctions, corners and structural supports should be constructed as such adequate cleaning can be done easily.
Best Practice: some facilities has sloped / curved juncture between floor and walls, to minimize accumulation of dust.

b) Cavity walls or walls constructed from soft materials should be avoided as they are potential source of pest harbourage.

c) Regular repair should be done for the walls to avoid any paint flakes, etc. resulting in cross contamination of food material during handling.
Best Practice: Protective guards can be fitted where wall/structure damages can occur.

3.3 **Floor**:

a) Floor shall be constructed with non-porous, non-corrosive material, resistance to cleaning chemicals, easily cleanable and managed to prevent water accumulation.

b) Floor shall be designed to avoid stagnant water. The slope of floor should be such that water flows directly to drains. Where high and low risk areas exist, slope shall run from high to low risk area.

c) Floor shall be sufficiently robust to withstand the working activities and be prevented from damage.

3.4 **Ceiling & Overheads:**

a) Ceiling and overhead structures shall be designed and constructed to prevent accumulation of dirt and to facilitate access for cleaning.

b) Ceiling and overhead structures should be free of excessive dust, dirt and cobwebs.

c) Where there are fans, regular and proper cleaning and maintenance program should be present.

3.5 **Windows**:

a) Window glasses should be protected to avoid glass cross contamination with food materials during food handling.
Best Practice: Shatter proof film are used

b) Windows and skylights which are not used for ventilation should be non-opening, sealed and protected.

c) Windows required for ventilation shall be screened with mesh or net to avoid entry of flying insects. The screening shall be non-opening and fully sealed to structure. Any gap or holes or broken parts thus found shall be replaced or repaired immediately.

d) The screenings should be regularly cleaned.

3.6 **Doors**:

a) Doors shall be close fitting, proofed against insect entry and shall be maintained in good repair conditions at all times.

b) Doors should be closed at all times if not in use.
Best Practice: All doors fitted with self-closing system

c) External doors shall not open directly into manufacturing, storage or packing area; except in case of emergencies.
d) Gaps around dock levelling platforms shall be adequately proofed to prevent pest entry.

3.7 **Ventilation**:
a) Adequate ventilation shall be provided to prevent condensation or excessive dust or mold growth.
b) Ventilation system shall be designed such as air moves from 'clean to 'dirty' areas and is not drawn back to clean manufacturing area.
c) All vents shall be screened to prevent insect entry and shall be maintained clean.

3.8 **Drainage:**
a) Drains shall be of adequate size for the purpose, free flowing and adequately covered with fitted with traps, in order to prevent problem with backflow and odours.
b) Drains shall be accessible for cleaning and maintenance.
c) Fixed machinery shall not be stored directly over or under a drain.
d) Drainage direction shall not flow from a contaminated area to clean area and from high to low risk area with no provision of backflow.

Drain trap - SS

3.9 **Location of equipment:**
a) Equipment shall be located to permit accesses for operation, cleaning and maintenance
b) Equipment should be away from wall and off the floor for easy and adequate cleaning and inspection.

3.10 **Laboratory practices:**
a) In house laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products.
b) They shall not open directly into the production areas.

3.11 **Storage of food, packaging materials, ingredients and non-food chemicals**
a) Storage areas shall be dry and well ventilated.
b) Raw material like sugar, pectin, Iodised salt ,spices, eggs should be kept on plastic or metal pallets.

c) All pallets should be away walls and off the floor for easy and adequate cleaning and inspection; and to avoid any pest harbourage.
d) Flavors, if used, should be kept on pallets or in racks in cold room at appropriate temperature specified by the supplier.
e) Separate area shall be defined to keep non-conforming materials.
f) A separate, secure (locked or otherwise access controlled) storage area shall be provided for cleaning materials, chemicals and other hazardous substances.

4 Utilities – Air, Water & Energy

4.1 **Water supply:**

a) The quantity and supply of water shall be sufficient enough to meet production processes.
b) Water shall be potable in nature, as per IS:10500.
c) Water used as a product ingredient, including as ice and steam (including culinary steam) or in contact with products or product surfaces shall meet specified quality and microbiology requirements relevant to the product.
d) Water storage tanks shall be regularly inspected for clean condition and appropriate action taken where necessary.
e) Where water supply is chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specification.
f) A program should be developed to clean and sanitize water pipelines.
g) Separate supply system shall be there for potable and non-potable water sources. Proper identification of potable and non-potable water pipelines shall be maintained.
Best Practice: Separate color coding or labelling
h) Non-potable water pipelines shall be prevented from reflux into the potable system.

4.2 **Boiler chemicals :**

a) Boiler chemicals if used shall be:-
i. Approved food additives which meet relevant additive specification; and should be food grade.
ii. Which have been approved by relevant regulatory authority (National Topological centre) as safe for use in water intended for human consumption .
b) Boiler chemicals shall be stored in a separate, secure (locked or access controlled) area when not in immediate use.

4.3 **Air quality and ventilation :**

a) Ventilation (natural or mechanical) shall be provided to remove excess or unwanted steam, dust and odours and to facilitate drying after wet cleaning.
b) Air handling unit should be fitted in process hall.
c) Protocols for air quality monitoring and control shall be established in areas where products which support growth or survival are exposed.
d) Ventilation system shall be designed and constructed such that air does not flow contaminated or raw areas to clean areas.
e) Air handling system should be monitored and subject to routine maintenance, cleaning and disinfection.
f) System shall be accessible for cleaning, filter changing and maintenance. Air filters shall be changed at an appropriate frequency to ensure their efficacy and so that they do not become a source of contamination.
Best Practice: An air quality monitoring program should be implemented to ascertain effective interval for changing filters.

g) All vents shall be screened and of a design to prevent pest entry.

h) Roof ventilators should be provided in storage godowns.

4.4 **Cold store facility**

a) Product temperature shall be monitoring and data logger should be placed and reports are generated appropriately.

b) DG power Backup shall be available.

4.5 **Lighting**

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

b) Lights shall be positioned so that they do not create a breakage contamination hazard during lifting operation involving forklift trucks or other mechanized devices.

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Protective covering on tube lights and bulbs

Density of Light at various Processing areas

Functional area	LUX*
Product inspection	540
Packaging	540
Processing hall	220
Locker & Rest rooms	220
Raw material storage	220
Finished goods storage	220
Maintenance area	110
Laboratory	300

****As per codex - RECOMMENDED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE***

4.6 **Waste Disposal:**

a) System shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products, production areas and environment.
b) Separate area to be defined for keeping waste.
c) Containers for waste and inedible or hazardous substances shall be :
   i. Clearly identified for their intended purpose
   ii. Located in a designated area
   iii. Constructed of impervious material which can be easily cleaned and sanitized.
   Best Practice: Preferably of plastic or SS bins.
   iv. Closed when not in immediate use
   v. Locked when the waste may pose a risk to the product
   vi. Polyethylene bag collected with waste should be kept inside the waste bins.

Best Practice: Different color dust bins shall be used for different wastes types like wet, dry, edible , non-edible, etc.

Waste management and removal

d) Provision shall be made for the segregation, storage and removal of waste.
e) Accumulation of waste shall not be allowed in food handling or storage areas. Removal frequencies shall be managed to avoid accumulation, with a minimum daily removal.
f) Removal and destruction shall be carried out by approved disposal contractors.
g) Records of waste should be maintained.

5 Equipment Suitability, Cleaning and Maintenance:

5.1 **Hygienic design:**

a) Equipment should be able to meet established principles of hygienic design, including smooth, accessible, cleanable surfaces, self-draining in wet process areas.
b) Risk assessment shall be conducted as part of equipment selection process.
c) Piping and ductworks shall be cleanable, drainable and with no dead ends.
d) Machinery, pipelines, equipment, holding vessels, tanks and silos shall be designed to prevent the accumulation and retention of the product and debris.
e) Equipment shall be designed to minimize contact between operators' hand and the products.

5.2 **Product contact surfaces:**

a) Be corrosion resistant to both product and cleaning and disinfection materials.
Best Practice: Metal product contact surfaces made preferably of stainless steel.

b) All welded joints and seams shall be smooth to the surface and free from pits and weld spatter

c) All hoses, taps, cross connections or similar sources of possible contamination of water supply shall be equipped with anti-backflow devices.

d) Seals, gaskets, O-rings and joint rings shall be designed to minimize product contact and shall be cleanable. All seals , gaskets ,O rings are to be disinfected with chlorine before use.

Ghee settling tank

Butter churn with Trolley

5.3 **Preventive maintenance:**

a) The preventive maintenance program shall include all devices used to monitor and/or control food safety hazards. For eg. Screens and filters (including air filters), magnets, metal detectors.

b) Corrective maintenance shall be carried out in such a way that production on adjoin line or equipment is not at a food safety risk.

c) Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.

6 Management of purchased materials:

6.1 Selection and management of suppliers:

a) Define process for selection, approval and monitoring of suppliers. The process used shall be justified by hazard assessment, including the potential risk to final product, and shall include:

i. Assessment of supplier's ability to meet quality and food safety expectations, requirements and specifications.

ii. Description of how suppliers are assessed

iii. Audit of the supplying site prior to accepting materials for production

iv. Appropriate third party certification

v. Monitoring the performance of supplier to assure continued approved status. Monitoring may include conformance to material or product specification, meeting COA requirements, satisfactory audit outcomes.

vi. Supplier approval shall specify both the supplier location and material being supplied.

6.2 Incoming material requirements (raw/ ingredients/packaging)

a) Delivery vehicles shall be checked prior to, and during, unloading to verify that quality and food safety of the material has been maintained during transit. (For e.g. seals are intact, free from infestation, temperature records, etc.)

b) Materials shall be inspected, tested or covered by COA to verify conformance or use. The method of verification shall be documented. The inspection frequency and scope may be based on the hazard presented by the material and the risk assessment of specific supplier.

c) Materials which do not conform to relevant specifications shall be handled under a documented procedure which ensures they are prevented from unintended use.

d) Packaging design and material shall provide adequate protection for products to minimize contamination, prevent damage and accommodate adequate labeling.

6.3 Supplier performance monitoring

a) Procedure shall be in place to ensure approved supplier provide documented evidence (COA) accompanying the delivered material to provide assurance that the material confirm the specification and help reduce/eliminate the incoming testing.

b) Performance shall be reviewed at regular schedule and shall include:-

i. Consistency of on line delivery, accompanying documents completeness and accuracy

ii. Material specification data sheet

iii. Quality

iv. Support on Post receipt (on floor) quality failures

c) The results of performance review shall be documented including the corrective and preventive action plan, the completion and effectiveness of actions being taken.

d) Approved supplier those fail to meet the agreed performance should be re-evaluated for their suitability.

7 Measures for Prevention of Cross Contamination

7.2 **Microbiological cross contamination, includes:**

a) Structural segregation- physical barriers, walls, separate buildings
b) Traffic patterns or equipment segregation- people, materials, equipment and tools
c) Separation of raw from finished or ready to eat (RTE) products

7.3 **Physical Contamination:**

7.3.1 **Glass :**

a) Use of glass, ceramics, porcelain and other hard and brittle material shall be minimized in manufacturing and storage areas.
b) Where glass and/or brittle materials are used, periodic inspection requirements and defined procedures in case of breakage shall be in place.
c) Glass and brittle material shall be avoided where possible, ideally with exception from light fittings and glass packaging lines there should be no glass items anywhere in manufacturing, packing and storage areas.
d) Where glass or hard plastic do exist, procedures shall be in place to prevent contamination and deal with any incidence.
e) Glass register- all glass in manufacturing, packing and storage areas shall be risk assessed and listed in a register.

7.3.2 **Wood**:

a) The use of wood for utensils, tools including maintenance equipment shall be minimized in product handling areas.
Best Practices: The use of plastic or metal pallets/ racks are preferred.

7.4 Metal detectors shall be able to detect ferrous, non-ferrous and stainless steel metals.

7.5 Pre-production start up check should be implemented for identified hazards; such as blades, nylon support, packaging material use on line, belts etc.

8 Cleaning and Sanitizing

8.1 Cleaning and sanitizing agents and tools :

a) Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instructions.
b) Tools and equipments like scrubbers , brushes , plastic brooms, vacuum cleaners etc. should be of hygienically designed and maintained.

Cleaning brushes

Cleaning mobs

Cleaning Tools with scrubber

8.2 Cleaning and sanitization program:

8.2.1 **Cleaning and sanitizing program shall specify at a minimum**

a) Areas, items of equipment and utensils to be cleaned and/or sanitized
b) Responsibility for the task specified
c) Cleaning and sanitizing method and frequency
d) Monitoring and verification arrangements
e) Post clean inspections
f) Pre-start up inspection

8.2.2 **Cleaning methods**

a) Requirements for cleaning shall be detailed in documented procedures and shall be readily available for people involved in cleaning.
Instructions shall include:

i. Frequency of cleaning
ii. Equipment disassembly and re-assembly instructions
iii. Cleaning methodology (CIP or COP system)
iv. Cleaning chemicals concentration
v. Contact time and temperature

b) Potable water shall be used for cleaning of food contact surfaces.

c) Programs for CIP systems shall be defined and monitored (including type, concentration, contact time, temperature of any chemical used).

Best Practices:
The cleaning and sanitation procedure used for each piece of equipment with defined frequency

EQUIPMENT	FREQUENCY	PROCEDURE
Butter Melting Vat	Daily once Weekly	**3A Step Hot COP** **7E Step Hot COP**
Ghee Kettle	After every two batches Alternate Days	**3A Step Hot COP** **7E Step Hot COP**
Prestratification Tank	Weekly	**7A Step Hot CIP**
Ghee Storage Tank, Settling Tank	Monthly	**7A Step Hot CIP**

Best Practices:
For 3 step and 7 step HOT COP

3A STEP HOT COP – For Ghee Kettle and Butter Melting Vat		
S.No.	**Step**	Description
1	**Pre- rinse**	Rinse with hot water
		Removal of loose soil, residues & hard deposits
2	**Hot Caustic**	Soak with Min. 0.6-0.8% caustic at 75-80°C for 2 hours
		Removal of loose soil, residues & hard deposits
3	**Hot water rinse**	Rinse with hot water till it becomes alkali free

7E STEP HOT COP – For Ghee Kettle and Butter Melting Vat		
S. No.	**Step**	Description
1	**Pre- rinse**	Rinse with hot water
2	**Hot Caustic**	Soak with Min. 0.6-0.8% caustic at 75-80°C for 2 hours
		Removal of loose soil, residues & hard deposits
3	**Hot water rinse**	nse with hot water for atleast 10 minutes till it becomes alkali free
4	**Acid Rinse**	Soak with Min. 0.6-0.8% acid at 75-80°C for 30 minutes
		Removal of loose soil, residues & hard deposits
5	**Fresh Water Rinse**	termediate fresh water rinse till the equipment becomes acid free
6	**Hot Caustic**	Soak with Min. 0.6-0.8% caustic at 75-80°C for 10 minutes
7	Hot water rinse	Rinse with hot water till it becomes alkali free

Best Practices:
For 3 step and 7 step HOT CIP

7A STEP HOT CIP		
S. No.	**Step**	Description
1	**Pre- rinse**	With fresh water at 45-50°C for 3 minutes
		With recup water at 45-50°C for 5 minutes
2	**Hot Caustic**	Min. 1-1.2% caustic at 75-80°C for 10 minutes
3	**Fresh water rinse**	ermediate freshwater rinse (preferably at 45-50°C) for 2 minutes #
		On delay time **
		Rinse with fresh water (preferably at 45-50°C) till complete removal of caustic results + 2 minutes extra time
4	**Acid**	Nitric acid of 0.8-1% at 50-60°C for 6 minutes
5	**Fresh water rinse**	ermediate freshwater rinse (preferably at 45-50°C) for 2 minutes #
		On delay time **
		Rinse with fresh water (preferably at 45-50°C) till complete removal of caustic results + 2 minutes extra time
6	**lot water sanitation**	nitize with hot treated water at 85 °C for 15 min. or at 80°C for 20 min
7	Fresh Water Rinse	nal rinse with treated water till the equipment is cooled to <35°C.

8.2.3 **Verification as to the effectiveness of cleaning shall include;**

a) Visual inspection
b) Analytical methods like:-
   i. Check pH of rinse water to confirm removal of chemicals residue
   ii. Swabbing using conventional microbiological swabs or rapid methods based on ATP
   iii. bioluminescence technology.
c) Cleaning record shall be maintained for the same period as manufacturing records

9 Pest Control Management

9.1 Pest control programs:

a) Establishment shall have a nominated person to manage pest control activities and/or deal with external appointed contractors.
b) Major pest activities : rodent , lizard , cockroaches , files , insects; shall be controlled.
c) Pest management programs shall be documented and shall identify target pests and address plans, methods, schedules, control procedures and where necessary, training procedures.
d) Program shall include a list of chemicals which are approved for use in specified areas of the establishment.
e) Records of pest management are to be maintained.

9.2 Preventing access:

a) Building shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed.
b) External doors, windows, ventilation openings shall be designed to minimize the potential of pest entry.
c) External doors shall be kept closed when not in use.

d) Site external and internal environment, storage facilities, equipment and associated ancillary areas (including waste handling areas, drainage and overheads) shall be kept clean and free of product accumulations to prevent pest infestations.

9.3 Harbourage and infestations:

a) Storage practices shall be designed to minimize the availability of food and water to pests.
b) Material found to be infested shall be handled in such a way to prevent contamination of other materials, products or the establishment.
c) Potential pest harbourage (e.g. burrows, undergrowth, stored items) shall be removed.
d) Where outside space is used for storage, stored items shall be protected from weather or pest damages (e.g. bird dropping).

Glue traps

Rodent Box sample

Fly catcher

9.4 Monitoring and detection:

a) Place of detectors and traps in key locations to identify pest activity.

b) Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products and facilities.
c) Gluel traps may be used in manufacturing areas and Rodent baits outside in premises shall be inspected daily so that captured pests may be removed.
d) Use of UV light traps (Electronic fly killers) is used where applicable and shall be emptied regularly
e) External bait stations shall be positioned to keep pest away from building entrances. It is recommended that bait station be placed every 25 meters around the perimeter of the building.

9.5 Eradication :

a) Eradication measures shall be put in place immediately after evidence of infestation is reported.
b) Pesticide use and application shall be restricted to trained operatives and shall be controlled to avoid product safety hazards.
c) Only fully trained qualified personnel should be permitted to apply pesticide application.
d) The use of insecticide within food factories shall be kept to minimum or avoided.
e) Records of pesticide use shall be maintained to show the type, quantity and concentration used; where, when and how applied, and the target pest. These chemicals shall be approved to be used in country.
f) All chemicals used for pest control measures, shall be accurately labelled and stored securely away from raw materials.

10 Personnel Hygiene and Employee Practices

10.1 Personal cleanliness

a) Personnel in food production areas shall be required to wash and, where required, sanitize hands:
   - On entry to all manufacturing area
   - Before commencing work
   - At an appropriate frequency during the day in the place of work
   - After handling raw, unprocessed ingredient, eg milk, cocoa beans
   - After handling allergens of allergen products
   - After cleaning and sanitizing plant and utensils
   - When hands are soiled
   - After visiting toilets
   - After handling refuse or rubbish
   - After coughing or sneezing
   - After eating

Steps for washing hands

10.2 Personal behaviour

a) Finger nails shall be kept clean and trimmed
b) Permissibility of eating, drinking and chewing in designated areas only
c) Permissibility of personal items, such as smoking materials, medicines, in designated areas only
d) Prohibition of the use of nail polish, false nails and false eyelashes
e) Prohibition of the writing materials behind ears. When pen or pencil is required to continuously monitor records during processing; the items should be kept at their designated places. The number of such items should be controlled and monitored daily before production start-up.
f) Maintenance of personal lockers so that they are kept free from rubbish and soiled clothing
g) Prohibition of storage of product contact tools and equipment in personal lockers

10.3 Work wear and protective clothes:

a) Dedicated protective clothing shall be provided for personnel working in areas where there is cross contamination risk; such as Microbiology lab, effluent treatment plant.
b) All visitors entering manufacturing area shall be provided with company issued protective clothing; such as, gloves, aprons, hair nets, shoes/ shoe covers; wherever applicable.
c) Personal protective equipment where required shall be designed to prevent product contamination and maintained in hygienic condition.

Disposable cap *Mask* *Gloves* *Apron with knitted cuffs*

10.4 Health, medical requirements:

a) Medical screening or checking shall be carried for all new employees (permanent or contractual), especially for those employed on food handling areas.

b) Employees shall report to their respective in-charges on the following conditions for possible exclusion from food handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharge from ear, eye or nose; any other infectious disease.

c) A health check questionnaire shall be completed by all visitors and contractors prior to entering manufacturing, packing, and storage

10.5 Employee facilities

10.5.1 **Toilets :**

a) Toilets shall not open directly into manufacturing, product handling or storage areas

b) Toilets shall be hygienic design and provided in accordance with statutory requirements and be adequately ventilated.

c) Toilets and washrooms shall be fitted with self closing doors. Each shall be provided with hand washing, drying and sanitizing facilities.

10.5.2 **Hand wash facilities** :

a) Hand wash stations shall have non-hand operated, preferably knee or photoelectric operated.

b) An adequate number of liquid soap dispenser and bactericidal sprays shall be provided at all hand wash stations.

c) Provision should be present to dry the washed hands; preferably through hand driers; roller towels or paper towels.

d) Waste receptacles like used paper rolls shall be provided at all hand wash stations.

e) Hand wash stations shall be provided at the entrance of all food handling areas

f) Hand wash stations shall be adequate for the volume of personnel entering during peak times, i.e. start of shifts, start and end of breaks.

g) Notices reminding personnel on hand washing or sanitizing should be posted in each toilet, urinal area, canteen area or each entrance of manufacturing.

Foot operated tap

Sensor based taps

Liquid soap dispenser

Sanitizer dispenser

10.5.3 **Canteen / Food eating area/ personal Lockers:**

a) Employee own food and personal belongings shall be stored in a separate designated area away from manufacturing area.
b) Facilities shall be provided for personnel for taking meals, refreshments either in a canteen or designated area away from manufacturing, packing and storage operations.
c) Protective clothings or company shoes if used shall not be kept with the personal clothings and shoes.

11 Rework Management :

a) Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance is maintained.
b) Rework shall be clearly identified and/or labeled to allow traceability. Traceability records for rework shall be maintained.

c) Rework is incorporated into a product as an 'in process step', the acceptable quality, type and conditions of rework use shall be specified.

12 Product Recall Procedure and Traceability

a) A recall may be initiated after the initial investigation of reported incident at manufacturing unit or complaint/s received from consumers or customers or any other sources.
b) As soon as the issue is acknowledged that could potentially lead to product recall or withdrawal; the issue must be immediately reported to the senior manager of the function and the Incident management team is notified.
c) The company shall immediately inform the local FSSAI authorities, if it considers or has reasons to believe that a food which is placed in market may be unsafe for consumers.
d) Traceability system shall be in place to identify production lots in relation to batches of raw materials , packaging materials , processing, packaging and delivery.
e) System shall be in place to identify incoming raw material and packaging materials supplier
f) Identification of distribution route of end product.
g) All records are to be maintained
h) Mock-recalls shall be carried out once in year; to validate the efficiency of traceability system.

Suggested Reading:

Product recall procedure shall be as per FSSAI recall protocol mentioned in Food Safety and Standards (Food Recall Procedure PART III Section 4) Regulations.

13 Product Information/Consumer Awareness :

a) Information may be provided by labelling or other means, such as company websites and advertisements, and may include storage, preparation and serving instructions applicable to the product
b) Labels shall have clear instructions to enable next person in food chain to handle, store, and use the product safely.

14 Food Defense, Biovigillance, And Bioterrorism

a) Each establishment shall assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures.

Access control

b) ***P***otentially sensitive areas within the establishment shall be identified, mapped and subjected to access control.
c) Where feasible, access should be physically restricted by use of locks/restricted entries, electronic card key or alternative systems.
   i. Water tanks shall be locked
   ii. All dead ends are to be capped
   iii. Entry should be restricted. Only authorised person should enter in manufacturing areas

15 Management and Supervision :

a) Appoint food safety team leader
b) Define food safety policy along with food safety objectives
c) Responsibilities & Authorities are to be defined.
d) Reviews on various activities should be done; such as- costumer/consumer complaints, internal & external audits, etc.

16 Food Testing Facilities :

a) A well-equipped, modern laboratory for testing of food materials / food for physical, microbiological and chemical analysis in accordance with the specification/standards laid down under the rules and regulations shall be in place preferably inside the premise for regular / periodic testing and whenever required.

Lab shall at least have testing facilities for Reichert Meissel Value (RM), Butyro – refractometer reading (BR) , Free fatty acid(FFA), Baudouin test and Moisture.

b) If there is no in house laboratory facility, then regular testing shall be done through an NABL accredited laboratory. In case of complaints received and if so required, the company shall voluntarily do the testing either in the in-house laboratory or from a designated lab outside.

17 Validation Procedures

a) Laboratory, whenever using non-standard methods or a standard method beyond the stated limits of operation is required to validate such test methods.
The guidance document on Validation of Test Methods, NABL 212 may be referred.
b) Validation of a method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the analytical results.
c) These procedures should be clearly stated in the documented method so that the user can assess the suitability of the method for their particular needs.

18 Audit, Documentation and Records

a) Internal audit system shall be in place and should be defined with:-
   - Criteria of audit
   - Scope
   - Frequency
   - Method of audit
   - Reporting non-conformance
   - Correction and correction on timely manner
   - Follow up activity include verification of corrective action
   - Analyze the results if verification of external & Internal audits.
   - Report to results of audits.

19 Training

a) All food handlers (permanent or contractual) are to be assessed for existing competence /awareness / skills / knowledge.
b) All persons are to be trained for food safety.
c) Training program should be developed with training calendar.
d) Systems should be in place for assessing effectiveness of training.
e) Records of training are to be maintained.

20 Non Conformance Management:

a) Procedure shall be established and maintained
b) Procedure shall include following in case of deviation in PRP/OPRPS/CCPS :
    i. Review of Non – review conformities / customer complaints
    ii. Determine the cause Non – conformance
    iii. Consequences in terms of food safety and can be handled potential unsafe product
    iv. Preventing re-occurrence
    v. Identifying and implementing the appropriate actions.
    vi. Evaluation to be recorded.
    vii. Take necessary actions and all actions are to be approved by responsible person.
    viii. Review action taken for effectiveness.

21 Customer Complaints Handling

a) Receive complaint on toll free number or telephone number or through Email . Information to be communicated to concerned person.
b) Go through complaint details,
c) Decide whether site visit is required. The decision shall be based on the type of complaint, extent of damage etc. If site visit is required, nominate a person for the visit.
d) Take appropriate correction /corrective action.
e) Gather additional information directly from the customer and the reference samples available in the factory. If necessary, get the sample re-analyzed and prepare technical report.
f) Take Corrective Action based on the gathered information and implement the corrective action.
g) Inform the customer/concern person about the findings and corrective actions suitably seeking further feedback
h) Verify the corrective action and based on customer's feedback complaint shall be closed.

V. Important Control Measures to Counter possible Stepwise Hazards

S. No.	Steps	Hazards	Attributes	Control Measures	Records
1	Raw Material specification		Raw Material shall meet specified standards	COA & Testing	COA & testing records
2	Raw Material Storage	Physical - Extraneous matter (Black spec, Foreign Particle, dust , dirt etc. due to poor storage , environment		Effective PRPS implementation	
		Chemical : Ammonia gas form refrigeration lines leakages		Preventive maintenance of equipment's	
		Biological : Coliforms , Clostridium Botulinium, Shigella ,S,Auereus ,Listeria , Yeast & Mold and aerobic spores due to improper storage temperature		Storage temp.	
3	CIP/ COP of Tanks (e.g. Storage Tank, Butter Melting vat etc.), Clarifier, Filling/Packing Machine	Physical - Extraneous matter (Black spec, Foreign Particle, dust , dirt etc. due to poor storage , environment	CIP shall be done as per recommended recipes CIP effectiveness should be ensured	Effective implementation of PRPS,	Housekeeping check sheet , Verification of records
		Chemical: Probable Cross contamination from remaining cleaning agent residues.		Cleaning & Sanitization PH evaluation of rinse water after cleaning to ensure no chemical residue.	Cleaning records , Bio trace records
		Biological: Coli forms ,Clostridium Botulinium, Salomonella ,E.Coli , Yeats &Mold / Aerobic spores due to improper cleaning		Cleaning & sensitization Swabs analysis after cleaning Microbiology of butter	Cleaning records, Bio trace ATP record, Micro records
4	Sour butter	Physical - Extraneous matter (Black spec, Foreign Particle, dust , dirt etc. due to poor storage , environment		Effective implementation of PRPS	housekeeping sheet GHK audit record
		Chemical -Lactic acid %		Sour Milk	Milk inspection record Timely reception of raw milk
		Biological: Coli forms ,Clostridium Botulinium, Salomonella ,E.Coli , Yeats &Mold / Aerobic spores due to improper cleaning		Cleaning & sanitization Inspection of raw milk Ghee boiling	Micro analysis records Swab bio trace record Use of good quality of butter
5	Transfer & Melting of butter	Physical : Probable presence of extraneous e.g. black specs, stones, glass, fragments etc. due to Envoirmental , personnel	Butter melting temperature	Effective implementation of PRPS, Butter melting temperature	Housekeeping check sheet, GHK audit record, Temperature monitoring records
		Chemical : Probable Cross contamination from remaining cleaning agent residues		Cleaning & Sanitization PH evaluation of rinse water after cleaning to ensure no chemical residue.	Cleaning records
		Biological : NA			

6	Boiling to 110 C (Ghee Cooking)	Physical : Probable presence of extraneous e.g. black specs, stones, glass, fragments etc. due to Envoirmental , personnel	To monitor the temperature of ghee cooking	Effective implementation of PRPs	Housekeeping check sheet GHK audit record
		Chemical : Probable Cross contamination from remaining cleaning agent residues, Free Fatty acid : Oleic acid due to improper cooking		Cleaning & Sanitization, Ph checking of rinse water, Appropriate temperature to be maintained at 110 o C	Cleaning records Temperature monitoring records
		Biological : NA			
7	Filtration	Physical : Extraneous matter(Black spec, Foreign Particle, Nylone thread due to damaged filter, Ghee residue due to damaged filter	Ghee shall be transferred to settling tank through a sanitary filter of 90 mesh	Effective implementation of PRPs To check for cleanliness and intactness of filter mesh	Housekeeping check sheet Pre-start-up check sheet Filter integrity & cleanliness records
		Chemical : NA			
		Biological : NA			
8	Settling in tank	Physical: Probable presence of Extraneous matter e.g. Black specs, iron, stones, threads etc. Due to Envoirment / personnel, Fine Ghee residue due to damaged filter cloth	Ghee at specified temperature shall be allowed to stand undisturbed for specified time	Effective implementation of PRPs Ghee pass through 90 mesh filter cloth To monitor the time & temperature of settling	Housekeeping check sheet GHK audit records Prestart up check sheet Time & temp. records
		Chemical : Cross contamination due to residue of cleaning chemicals		Cleaning & sanitization , Ph check of rinse water after cleaning	Cleaning records Verification records
		Biological : NA			
9	Clarification with centrifugation	Physical : Very fine particles in ghee due to improper settling		To monitor the temperature of clarification RPM 8500 to be maintained Replacement of torn / damaged cloth	Pre-start-up check sheet Clarification temp. records
		Chemical :NA			
		Biological : NA			
10	Online Testing	Physical : NA	Product shall meet all physico chemical parameters	To check essential parameters as per requirement.	Testing & analysis records
		Chemical :NA			
		Biological : NA			
11	Filling in tins	Physical : Probable presence of ,Extraneous matter e.g. dust, dirt, stones, threads, insects etc.	Ghee to be filled at specified temp. in tin containers and sealed	Effective implementation of PROs cleaning of tins	Inspection of tins
12	Filling in poly pack	Physical : NA	Ghee to be filled at specified temp. in poly pack containers and sealed		
		Chemical- Polymer Migration		Approved Supplier, Annual testing through external agency for virgin polymer	Test report of polymer
		Biological : Colifroms due to cross contamination		Cleaning & sanitization, Poly film passed through UV light, UV lamps changed at every 2000 hrs	Cleaning records, Preventive maintenance record
13	Filling in poly jar	Physical : Probable presence of Extraneous matter e.g. dust, dirt, stones, threads	Ghee to be filled at specified temp. in poly jar containers and sealed	Use of clean poly jars Effective implementation of PRPs	Inspection of poly jars Housekeeping check sheet

14	Ghee filling, sealing labelling		Ghee to be filled at 45°C & sealed	To monitor the temperature of ghee First Pack Clearance - Batch Code, Net Weight, To check seal integrity, batch code and net weight.	Records of all checked parameters
15	Extraneous Matter Prevention	Physical		Metal Detector/X-ray M/c	Records of all checked parameters
16	Granulation	Physical: NA Chemical: NA Biological: NA	Granulation to be carried out at 25±2°C for 48 hours. Ghee shall have large number of small granules.	To check granulation time and temperature from Thermograph / Datalogger	Records of all checked parameters
17	Transfer to balance tank	Physical : Probable Presence of extraneous matter, cleaning brush fibers ,threads etc.		Cleaning & sensitization Product pass through muslin cloth 90 mesh	Filter cleaning /verification record Cleaning record
		Chemical : Probable Cross contamination from remaining cleaning agent residues due to unclean pipe lines		PH evaluation of rinse water after cleaning to ensure no chemical residue.	Cleaning record
		Biological: Biological: Coli forms ,Clostridium Botulinium, Salomonella ,E.Coli , Yeats & Mold / Aerobic spores due to improper cleaning			
18	Crating and cartooning	Physical : Probable come across of extraneous matter, etc. due to Unclean crates		Cleaning and use of clean crates	Cleaning crates records
		Chemical : NA			
		Biological : Cross contamination due to leaky pouches		Inspection and segregation of pouches	Inspection record
19	Storage	Physical : Probable come across of extraneous matter, etc. due to Unclean crates	Product shall be stored in cool & dry place away from sunlight.	Inspection and segregation of pouches, Cleaning and use of clean crates	Inspection record, Cleaning crates records
		Chemical : NA			
		Biological : Cross contamination due to leaky pouches , Probable microbial Contamination due less quantity of preservative		Inspection and segregation of pouches, Monitoring of ingredients and weighing quantity	Calibration of weighing scale records, Weightiest record of ingredients
21	Storage on Pallates	Physical: Cartons damaged due to improper pallets, nails appearance.	Maximum Stack height of product shall be fixed & maintained.	Pellatization as per good condition pallets	Quality report
22	Dispatch	Physical : NA		Vehicle condition & Cleanliness shall be checked before loading	Vehicle inspection check list
		Chemical : NA			
		Biological : NA			

VI. References

1) General requirements on hygiene and sanitation; Schedule 4; Part II; Food Safety and Standards (Licensing and Registration of Food Business), Regulations 2011
2) Codex code of practice: General Principles of Food Hygiene (CAC/RCP 1-1969)

Suggested Readings*:*

1) Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 http://www.fssai.gov.in/Portals/0/Pdf/Food_safety_and_standards_Food_product_standards_and_Food_Additives_regulation_2011_English.pdf

2) Food Safety and standards (Packaging and Labelling) regulation, 2011

VII. Annexures

Annexure 1

Ghee Testing Requirements

S.No.	Test Name	Requirement	Unit	Limit As PER FSSAI-2011
1	**Chemical Analysis**			
	Moisture	0.5	%	Max. 0.5
	Baouduin test	Negative	--	#
	Butyro Rafractometer R reading at 40 ° C	40 – 45	--	40 – 45 (Depend on location)
	Reichert Value	24		21 – 28 (Depend on location)
	Phytosterol acetate	Negative	Negative	#
	Polenske value	1- 2	1- 2	
	Free Fatty acid (Oleic acid)			
	Special Grade (Agmark Red Label)	Not more than 1.4	%	#
	General Grade (Agmark Green Label)	Not more than 2.5	%	#
2	**Aflatoxins**			
		NA	ug/kg	Total Aflatoxin NMT 30
	Aflatoxin B1		ug/kg	
	Aflatoxin B2	NA	ug/kg	
	Aflatoxin G1		ug/kg	
	Aflatoxin G2			
3	**Naturally Occuring Toxins Substances**			
	Agaric Acid		mg/kg	NMT 100
	Hydrocyanic Acid	100	mg/kg	NMT 5
	Hypericine	Absent	mg/kg	NMT 1.0
	Saffrole	Absent	mg/kg	NMT 10.0
		Absent		
4	**Pesticides Residues**			
	Inorganic Bromide (Determined and expressed as total bromidefrom all sources	5	mg/kg	NMT 5
5	**Heavy metals:**			
	Arsenic	1.1	mg/kg	MAX. 1.1
	Cadmium	1.5	mg/kg	MAX.1.5
	Copper	30	mg/kg	MAX.30
	Lead	2.5	mg/kg	MAX.2.5
	Mercury	1.0	mg/kg	MAX.1.0
	Methyl Mercury	0.25	mg/kg	MAX.0.25
	Tin	250	mg/kg	MAX.250

Annexure 3

Specific Regulatory Requirements

a) The standards of quality of ghee produced in a State or Union Territory specified in Food_safety_and_standards_Food_product_standards_and_Food_Additives_regulation_2011_English (Page 313).
b) Provided further that Ghee and Butter may contain Butylated hydroxyanisole (BHA) in a concentration not exceeding 0.02 per cent.

Suggested Readings:
Food safety and standards Food product standards and Food Additives regulation 2011

Annexure 4

Packaging and Regulatory Requirements

Product specific requirements

1. Packaging requirements for Milk and Milk Products

(a) Bottling or filling of containers with heat-treated milk and milk product shall be carried out mechanically and the sealing of the containers shall be carried out automatically.

(b) Wrapping or packaging may not be re-used for dairy products, except where the containers are of a type which may be re-used after thorough cleaning and disinfecting.

Suggested Readings:
Food Safety and standards (Packaging and Labelling) regulation, 2011

Annexure 5

FSMS Related Document & Record Templates:

Food Safety & Quality Policy (Template)

Top management has defined a food safety policy (as mentioned below) which:

• Is appropriate to the role of the organization in the food chain,
• Conforms with statutory and regulatory requirements and with mutually agreed food safety requirements of the customers,
• Addresses communication,
• Is supported by measurable objectives (as mentioned below),
• Has been communicated, implemented and explained to the all employees of the organization. Food safety policy posters printed in English and Hindi are displayed at all important locations in the organization. FSTL conducts survey periodically to assess the level of understanding of the policy amongst employees, and
• Shall be reviewed for continuing suitability once in a year.

As an illustrative example below:

(Company name) is committed to exceed expectation and need of its esteemed guests and ensure to provide them with safe and quality food and beverage as well as prompt and efficient service. The organization shall achieve above commitments through:
• Providing vibrant work environment that result in excellence.
• Establishing and reviewing food safety objectives for continual improvement in skills of the employees, processes and systems.
• Meeting requirements of customers as well as applicable statutory and regulatory requirements.
• Applying ISO 22000 principles in food safety management system that results in production of quality and safe food and beverage from receiving to serving the guest.

Food Safety & Quality Objective (Template)

Every Objective should be SMART:

S- SPECIFIC; M-MEASURABLE; A-ATTAINABLE/ ACTION ORIENTED; R-REALISTIC; T-TIME BASED

As an illustrative example below:

S.No.	*Objective*	*Target*
1	*To ensure that all employees are trained in food hygiene during the year.*	*Improvement by 2%*
2	*Increase in customer satisfaction index*	*Improvement by min. 1%*
3	*Reduction in numbers of unsatisfactory & rejected grades - C & D grades of food items from receiving to serving through validation & verification of all process CCPs & OPRPs by conducting microbiological testing.*	*Improvement by 2%*

Management Review Meeting (Template)

Name of Manufacturing plant: _____

Date: _____

Attendees:

Name	Designation/Area of Operation	Signature

S.No.	Review Topics	Discussion / Comments	Further Actions	Responsibility	Target date
1	Follow up actions from previous MRM (incl. Corrective & Preventive actions)				
2	Analysis of results of verification activities				
3	Changing circumstances that can affect food safety				
4	Emergency situations, accidents, reacall or withdrawls				
5	Reviewing result of system updating activities				
6	Review on communication activities, incl. customer feedback				
8	Results of Internal Quality Audits (incl. HACCP), external audits and inspection				
9	Supplier performances				
10	Reports on process & service non-conformance				
11	Assurance of food safety				
12	Performance objective of Processes & products for improving FS effectiveness				
13	New opportunities for improvement/ Resource requirements				
14	Review of Food Safety & Quality Objective and Policy				
15	Others				

Internal Audit Plan (Template)

S.No.	Process Area	Month/Year: _____											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Store areas- Raw material, ingredients, chemicals, finished product												
2	Process Area												
3	Housekeeping, Cleaning & Personal Hygiene												
4	Preventive Maintenance												
5	Internal Laboratory												
6	Management functions												
7	Packaging & Dispatch area												
8	Documentation												
9	Human Resource & Training												
10	Others												

Internal Audit Schedule (Template)

Date of Audit:
Standard of Audit:

S.No.	Process Area	Auditee(s) & Functional Department	Auditor(s) & Functional Department	Date	Time
1	Store areas- Raw material, ingredients, chemicals, finished product				
2	Production/Manufacturing Area				
3	Housekeeping, Cleaning & Personal Hygiene				
4	Preventive Maintenance				
5	Internal Laboratory				
6	Management functions				
7	Packaging & Dispatch area				
8	Documentation				

9	**Human Resource & Training**				
10	**Others**				

Internal Audit Observation & Non- conformance report (Template)

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

Areas Covered:

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

FSMS Team (Template)

S.No.	Name	Designation	Funtional Area	Qualification	Experience/Skills	FSMS Training done on	Responsibility

Product Information (Template)

S.No.	Description	Specifications
1	Product Category/Name	
2	Composition (Raw materials, Ingredients, etc.)	
3	General & Specific product specification	
4	Legislative requirements, Customer requirements	
5	Storage	
6	Labeling	
7	Transportation	
8	Product Shelf-life	
9	Packaging material	
10	Hazardous for any group of customers	
11	Food Category	
12	INTENDED USE	

Control of System Documents (Template)

S.No.	Document No.	Document Title	Issue/ Revision no.	Issue/Revised Date of document	Reason for Revision	Request Done by	Request Approved by	Funtional Area responsible/ Location

Product Recall record (Template)

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

Product Identification & Traceability (Template)

Traceability Detail Format

Product Description

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

Traceability Details

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

A. CIP Details

Equipment Name	CIP Details			Remarks
	Date	Time	Person responsible	

B.Ingredient Details

Material Description		Remarks
Name	Batch/Lot No.	

C. Water Treatment Details

Chemical/Material Description		Remarks
Name	Batch/Lot No.	

D. Primary Packaging

Material Description		Remarks
Name	Batch/Lot No.	

E.Manufacturing Details

Date	Shift	Cases Manufactured	CCP Compliance	Remarks

F. Analytical Details

Date	Shift	Analytical compliance%	Product blocked,if any	Remarks

G.Dispatch Details

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

Product Recall- Mock Drill report (Template)

Date of Drill:
Starting Time of Drill:
Closing Time of Drill:
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 Physical Verification:

Remarks:

Correction & 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:
Correction 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

Determination of Customer Satisfaction (Template)

We would like to know how well we are succeeding in meeting your needs. Following is the questionnaire about what you wanted from us. Answers will be treated with complete confidentiality. Please answer these questions using the scale (Please TICK that you choose).

('1' being the worst score; '5' being the best score)

S.No.	QUESTIONS	SCORE				
1	How well do we communicate with you?	1	2	3	4	5
2	Do we give you the information you need?	1	2	3	4	5
3	Do we answer your queries promptly?	1	2	3	4	5
4	Do we respond positively to your problems & suggestions?	1	2	3	4	5
5	Do you feel we have a concern for quality & food safety?	1	2	3	4	5
6	Do we deliver quality & safe products consistently and on time?	1	2	3	4	5
7	Do we anticipate your needs?	1	2	3	4	5
8	Have we increased your understanding of quality & food safety?	1	2	3	4	5
9	Do we work with you as a team?	1	2	3	4	5

Any other comments?

Name and Address

Training Calendar (Template)

S.No.	Topic of training	Month/Year: _____											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													

Training Need Identification (Template)

Name of employee: **Date of Joining:**
Qualification:
Designation: **Department:**
Key Responsibilities:

Training(s) Required

1	**Managerial**	
2	**Technical**	
3	**On the Job**	
4	**General/Others**	

Suggested Training iinstitutions (applicable for external trainings):

Any other suggestions:

Signatue of Dept. Head:

Below topics of training to be determined, but not limited to:

1. *Food safety policy*
2. *Food safety objective and targets*
3. *Actual or potential significant environmental impacts and unacceptable risks of the work activities*
4. *Food Safety and hygiene related issues*
5. *Compliance to legal requirements*
6. *Roles and responsibilities of employees to ensure effective implementation of food safety*
7. *Operational Control procedures*
8. *Emergency Preparedness and response requirements*
9. *Potential effects of deviation from documented procedures*

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 (Template)

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

Pre-employment medical record (Template)

Name of Candidate:
Father's name:
Address:
Date of Birth:
Designation applied For:
Age:
Name of hospital/laboratory tested:

Medical Examination

Heart : Chest : Abdomen : Blood Pressure : Eye Sight : C.N.S. :	Blood Group : Blood Sugar : Haemoglobin : T.L.C. : D.L.C.: P L M E
X.Ray Chest: E.C.G.:	Urine Examination: Stool:

Final Medical Report:	
Sugnature of Candidate	**Signature of Medical Examiner:** **Reg. No. of the Medical Examiner:**

Regular medical record (Template)

Name of employee:	
Date of medical test conducted:	
Next Medical test due on:	
Name of hospital/laboratory tested:	
Tests done for:	
Status of accceptance (Yes/No):	

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 Jewellery	Covered Hair	Clean outer garments / protective clothing	Clean Shoes/ shoe covers	Infectious Disease / Skin infection / Allergy, if any	No Tobacco/ Smoking / Chewing	Overall Hygiene Status upon examination (Yes/No)	Action needed on non-compliance	Re-examination status (Yes/No)
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
14															

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

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*

Glass & Brittle Plastic Monitoring record (Template)

S.No.	Item number	Item placed at	Condition (OK/Not OK)	Correction done	Remarks

Knife/ Other Utensil Monitoring record (Template)

S.No.	Item number	Item placed at	Condition (OK/Not OK)	Correction done	Remarks

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

List of Monitoring & 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

Pest Management Plan (Template)

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

Waste Disposal Record (Template)

S.No.	Amount of waste						Daily disposal (Yes/No)
	Chemica/ Hazardous waste	Food material waste	Package material waste	Other waste (Dry)	Other waste (Wet)	% of total waste	

Approved Supplier List -Latest (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 Material Inspection

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

Material Name:	
Supplier Name:	
Identification/Location of Supplier:	
Quanity received:	
Pack size received:	
Material Receipt Date:	
Transport Mode:	
Rejected (Yes/No):	
Reason for Rejection:	

PARAMETER EVALUATED	STATUS/RESULTS	Signature
Temperature (Degree Celsius)		
Visual Inspection Condition (OK/Not OK)		
Packaging & Labelling Condition (OK/Not OK)		
Production Date/Shelf Life Date/Expiry Date		
Vehicle Inspection Condition (OK/Not OK)		
Quality Lab Results (If applicable)		
Certificate Of Analysis (COA) received (Yes/No)		
Remarks		
Clearannce Date		
Authorized Signatore		

Incoming Vehicle Inspection Record (Template)

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

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

Authorized Singature

List of Monitoring & 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		

Fire extinguishers inspection record (Template)

Inspection date	Extinguisher No.	Type/Specification	Due date of re-filling	Actual date of re-filling	General condition	Signature

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	
Others, if any	
Quality Lab signature	

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	

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