A. TITLE, SCOPE AND APPLICATION

TITLE : FOOD SAFETY MANAGEMENT SYSTEM MANUAL

PURPOSE : This Food safety manual and related Food safety management system document referred there in are intended for the purpose of implementation of ISO 22000:2005 Food Safety Management System at Lactonova Nutripharm Private Limited, IDA Mallapur, Uppal Mandal, Hyderabad.

MANUFACTURING FACILITY & REGISTERED OFFICE:

Plot no: 81 (3), IDA Mallapur, Uppal Mandal, Hyderabad
R.R.District, Telangana - 500076, INDIA
EMAIL : regulatory@lactonova.com

SCOPE: The food safety management system defining in the manual is applicable for the Manufacture, test and supply of Food Supplement products in the form of tablets, capsules, powders and other health care products.

EXCLUSIONS:

1. Since Lactonova Nutripharm Private Limited manufactures the product as per the customer requirements /specification, Design & Development is excluded from the scope of audit.
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**C. ABBREVIATION**

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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>LN</td>
<td>Lactonova Nutripharm Private Limited</td>
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<tr>
<td>MD</td>
<td>Managing Director</td>
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<td>ST</td>
<td>Standard</td>
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<tr>
<td>TL</td>
<td>Team Leader</td>
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<td>MKT</td>
<td>Marketing</td>
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<td>PUR</td>
<td>Purchase</td>
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<tr>
<td>INC</td>
<td>Incharge</td>
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<tr>
<td>ADMIN</td>
<td>Administration</td>
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<td>ASSTS</td>
<td>Assistants</td>
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<td>MRM</td>
<td>Management Review Meeting</td>
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<tr>
<td>IQA</td>
<td>Internal Quality Audits</td>
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<tr>
<td>HOD</td>
<td>Head of the Department</td>
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<td>Q</td>
<td>Quality</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>Quality Assurance</td>
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<td>Production</td>
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<td>Responsibility</td>
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<td>A</td>
<td>Authority</td>
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<td>Doc</td>
<td>Document</td>
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<td>No.</td>
<td>Number</td>
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<td>TC</td>
<td>Test certificate</td>
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<tr>
<td>FSSP</td>
<td>Food safety System procedure</td>
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<tr>
<td>WI</td>
<td>Work instruction</td>
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<tr>
<td>SOP</td>
<td>System Operating Procedure</td>
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<tr>
<td>FSM</td>
<td>Food safety manual</td>
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<td>Dept</td>
<td>Department</td>
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<tr>
<td>FSMS</td>
<td>Food Safety management system</td>
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<td>CH</td>
<td>Chart</td>
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<td>CCP</td>
<td>Critical Control Point</td>
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<td>PRP</td>
<td>Pre Requisite Programmes</td>
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FOOD SAFETY POLICY

We are committed to produce Safe, Hygienic and high quality Food Supplements to meet the customer satisfaction by meeting statutory and legal requirements.

We also strive to continuously learn, improve and implement each positive development in every department.

FOOD SAFETY OBJECTIVES

- To give employees, a minimum of one training program in a month in handling, processing of the safe food supplements. (Responsibility level- Head RA &QA)
- None conforming in put materials not more than 5% per supplier of the total consignment per month. (Responsibility level- Executive Warehouse)
- To bring down the wastage of the raw material to 5% of the total production. (Responsibility level- Manager production)
- Customer complaints not more than 5% per month (Responsibility level- Head RA &QA)
2. INTRODUCTION TO THE MANUAL

This Food safety manual is prepared to address the requirements of the International Standard ISO 9001:2000. This Food safety manual form a part of overall Food Safety Management System being implemented by Lactonova Nutripharm Private Limited at their manufacturing facility located at IDA Mallapur, Uppal Mandal, and Hyderabad.

For the purposes of this Food safety manual and related Food safety system documents, the definitions given in ISO 22000:2005 shall apply.

Lactonova Nutripharm Private Limited has developed this Food safety manual in order to implement Food Safety Management System in accordance with the international standard ISO 22000:2005. This Food safety manual addresses all elements of ISO 22000:2005 and outlines the structure of documentation used in the Food safety System. It describes or makes reference to the Food safety system procedures, according to which the respective functions carry out its activities in a systematic and effective manner in order to, achieve the Food safety Policy and objectives of the organization.

Food safety manual document reference number and revision status is identified in page (1). This Food safety manual is prepared by the Team Leader and approved by the Director in accordance with the requirements of ISO 22000:2005.

Document issue control procedure for this manual is described in section 4 under sub-clause number 4.2.3.
3. INTRODUCTION TO THE ORGANISATION

GENERAL INFORMATION

Brief information of the company

Lactonova Nutripharm Private Limited is an Associate Company of Lactonova India. Lactonova India was founded in 2007 is engaged in marketing of Pharmaceuticals and Nutraceuticals, ethical formulation products. The company has contract manufacturing facilities to cater its manufacturing requirements.

Lactonova Nutripharm Private Limited was founded in 2013. It is engaged in manufacturing and marketing of Solid oral dosage formulations such as Tablets, Capsules, Dry Powders and Pellets.

Lactonova Nutripharm Private Limited endeavors to provide high quality Dietary, Nutraceuticals and Pharmaceutical formulation to cater the needs of patient. A team of highly qualified personnel of various disciplines are working to meet the customer requirements and to enhance the customers satisfaction and continuous improvement in quality.
4. FOOD SAFETY MANAGEMENT SYSTEM

4.1 General

Lactonova Nutripharm Private Limited established, documented, implemented and maintains a Food Safety Management System and continually improves its effectiveness in accordance with the requirements of the International Standard ISO 22000:2005.

To implement the Food safety Management System, Lactonova Nutripharm Private Limited has

a) Identified the processes needed for the Food Safety Management System and their application throughout the organization,

b) Determined the sequence and interaction of these processes

c) Evaluate Periodically, and update when necessary, the food safety management system to ensure that the system reflects the organization’s activities and incorporates the most recent information on the food safety hazards subject to control.

d) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective (detailed in various clauses of FMS and Food safety System procedures).

e) Ensured the availability of resources and information necessary to support the operation and monitoring of these processes.

f) Systems to monitor, measure and analyze these processes, and

g) Systems to implement actions necessary to achieve planned results and continually improve these processes.

The above processes are managed by Lactonova Nutripharm Private Limited in accordance with the requirements of ISO 2200:2005 and it includes the processes for management activities, provision of resources, product realization and measurement.

Note: Where Lactonova Nutripharm Private Limited chooses to outsource some of the processes that affect product conformity with requirements, Lactonova Nutripharm Private Limited ensures control over such processes. This has been addressed in purchasing process.
4.2 Food safety System documentation

4.2.1 General

The Food Safety Management System documentation includes:

a) Documented statements of a Food safety Policy in manual and related objectives.
b) A Food Safety Manual,
c) Documented procedures as required by the referred international standard,
d) Documents needed by Lactonova Nutripharm Private Limited to ensure the effective planning, operation and control of its processes which includes Food safety system procedures, Work instructions and SOP’s
e) Food safety Management system records required by the referred international standard as well as organization’s documented Food safety System.

Lactonova Nutripharm Private Limited has ensured that the established documented Food safety Systems are in relevance to:

a) The size of the organization and type of activities
b) The complexity of processes and their interactions, and
c) The competence of personnel

This Food safety manual

a) Defines the scope of the quality management system, including details of and justification for the exclusion made,
b) Provide reference of the documented procedures established for the Food safety management system,
c) Describes the interaction between the processes of the Food Safety Management System.

The structure of the Food Safety Management System is given below:

Level 1 – Food safety manual

FSM addresses various elements of ISO 22000:2005 in the context of their application to Lactonova Nutripharm Private Limited. It also outlines the structure of the documentation used in the Food Safety Management System and makes reference to the level 2 documents.

Level 2 – Food safety System Procedures
Food safety System procedures and SOPs - addresses procedures followed with respect to selected element(s) of above standards and for specific activities.

4.2.2 Control of documents

Documents of the Food Safety Management System are controlled in accordance with documented Food safety System procedure. It describes the structure of Food safety System documentation and defines controls needed:

a) To approve documents for adequacy prior to issue,
b) To review and update as and when necessary and re-approve documents,
c) To ensure that changes and the current revision status of documents are identified,
d) To ensure that relevant versions of the applicable documents are available at points of use,
e) To ensure that documents remain legible and readily identifiable,
f) To ensure documents of external origin are identified and their distribution controlled, and

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.3 Control of Food Safety System records

At Lactonova Nutripharm Private Limited, Food safety records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Food safety management system. Quality records are kept legible, readily identifiable and retrievable. Documented procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records.

5. MANAGEMENT RESPONSIBILITY

5.1 Management commitment

Top Management of Lactonova Nutripharm Private Limited is committed to the development and implementation of the Food Safety Management System and continually improves its effectiveness by:

a) Communicating throughout the organization - the importance of meeting customer as well as statutory and regulatory requirement (where applicable),
b) Establishing the Food safety Policy,
c) Ensuring that the Food safety objectives are established,
d) Conducting management reviews, and
e) Ensuring the availability of resource.
f) Food safety is supported by the business objectives of the organizations.

Business objectives: To enhance profits by reselling to current customers and getting new sales through customer referrals by improving customer satisfaction.
To increase productivity by improving product functionality, decreasing prices, improving service quality and convenience.

The top management of Lactonova Nutripharm Private Limited communicates the need of addressing the customer requirements in their field of activity and the top management’s interest in the same. In this endeavor awareness is given to employees with regard to the importance of strict adherence to documented Food safety System procedures, periodical audit of products and processes, monitoring and evaluation of food safety objectives (See page number 4).
The management initiates necessary actions to overcome deficiency in any of the above and this will form the means of achieving the set Food safety Policy and objectives.

5.2 Food safety Policy

Lactonova Nutripharm Private Limited has established the Food safety Policy as described in page-4 and this policy is appropriate to the purpose of the organization and is with a vision of organization’s future. It includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system. This policy provides a framework for establishing and reviewing quality objectives. Management with due delegation to key Personnel, ensure that the organization’s Food safety Policy is communicated and understood within the organization.

The Management review committee reviews the policy at appropriate time for its continuing suitability. To form a basis for review, Lactonova Nutripharm Private Limited will:

a) Evaluate the expected level of customer satisfaction relative to competition in its market place.
b) Conforms with both statutory requirements and with mutually agreed food safety requirement of customers
c) The role of organization in the food chain
d) Evaluate risks against achieving the organizational objectives.
e) Evaluate opportunities and need for continual improvement

5.3 Planning
5.3.1 FSM Objectives
At Lactonova Nutripharm Private Limited, Food safety objectives are established and documented, which is subject to revisions with the aim of achieving the Food safety Policy and to achieve continual improvement. These objectives are measurable and are consistent with the company’s Food safety Policy.

5.3.2 Food Safety Management System planning
The Food Safety Management System planning is carried out by ensuring availability of necessary checks and controls within the processes of the quality management system. These are documented in the QA documentation of various levels and are subjected to periodical review for ascertaining their continued suitability and effectiveness.

The integrity of Food Safety Management System is maintained whenever changes to the Food Safety Management System are planned and implemented as per the clause.

Responsibility, authority and communication

5.4.1 Responsibility and Authority
Responsibilities and authorities for all functions as given in the organization chart are defined and it is communicated to the concerned people in order to facilitate effective food safety management system.

5.5 Food safety team leader
QA Manager and Director Mr. Sampath Kumar Janardhan Chanda have been appointed as a corporate Food safety team leader for ISO 22000 food safety management systems implementation. Team Leader responsibilities and authorities are given below:

a) To Manage Food safety Team and organize its work
b) Ensure relevant training and education of the food safety Members
c) Ensuring that processes needed for the Food Safety Management System are established, implemented and maintained.
d) Reporting to top management of the performance of the Food Safety Management System and any need for improvement, and

5.6 Communication

5.6.1 External Communication

Lactonova Nutripharm Private Limited shall establish, implement and maintain arrangements for communication with
a) Suppliers and contractors
b) Customers or consumers in particular in relation to product information (including instructions regarding intended use, specific storage requirements and as appropriate, self life), enquires, contracts or order handling including amendments, and customer feedback including customer complaints.

c) Statutory and regulatory authorities.

Note: Designated personal shall have defined responsibility and authority to communicate externally any information concerning food safety. Information obtained through external communication shall be included as input to system updating and management review.

5.6.2 Internal Communication

At Lactonova Nutripharm Private Limited, good internal communication system is established that is necessary for the effective functioning of the Food Safety Management System processes. The internal communication systems are fax, phone, mails, display boards, memo, oral communication, MRM and letter correspondence.

In order to maintain the effectiveness of the food safety management system, the Lactonova Nutripharm Private Limited shall ensure that the food safety team is informed in timely manner of changes, including but not limited to the following
a) Products or new products
b) Raw materials, Ingredients and services
c) Production system and Equipments  
d) Production Premises, location of equipment, surrounding environment  
e) Cleaning and sanitation programmes  
f) Packing, storage and distribution systems  
g) Personal Qualification level and allocation of responsibilities and authorizations  
h) Statutory and regulatory requirements  

5.7 Emergency Preparedness  
Lactonova Nutripharm Private Limited has established an onsite Emergency Plan for Emergency Preparedness & Response to identify potential for and respond to Accidents and Emergency situations and for preventing and that can Impacts food safety.  

Personal safety equipments are provided to the employees, working in production sections and in other areas, as appropriate. Fire Extinguishers are provided at appropriate locations and are tested periodically.  
The emergency preparedness plan is tested once in a six months by conducting mock trials  

5.8 Management Review  
5.6.1 General  
The Management reviews committee and functional heads review the Food Safety Management System once in SIX months in the MRM (Management review meeting) to ensure its continuing suitability, adequacy and effectiveness  
The review committee evaluates the need for changes to the organization’s Food safety management system, including Food safety Policy and objectives.  
The Team Leader takes decision regarding the meeting date and agenda and communicates the same to committee members through circular / displaying notice board in advance.  
5.6.2 Review Input  
Input to management review includes current performance and improvement opportunities related to the following:  
a) Follow – up actions from previous management reviews.
b) Analysis of results of verification activities

c) Changing circumstances that can affect food safety

d) Emergency situations, accidents and withdrawals

e) Reviewing results of system-updating activities

f) Review of communication activities, including customer feedback and

g) Internal and External audits or inspections

5.6.3 Review Output

The outputs from the management review include action related to:

(a) Assurance of food safety

(b) Improvement of the Food Safety Management System.

(c) Resource needs

(d) Revisions of organization’s food safety policy and related objectives.

The results of the management review meeting are entered in Minutes of Meeting and action plan by the Team Leader and circulated to the functional Heads.

6. RESOURCE MANAGEMENT

6.1 Provision of Resource

Top Management of Lactonova Nutripharm Private Limited ascertains by periodic review, the resource availability and requirement to meet the situation that is influenced by factors such as

- Changing customer needs
- Scope for expanding business
- Need for technology up-gradation
- Improving work environment

Top Management shall ensure that resources needed (identified as above) are provided.

- To implement and maintain the Food Safety Management System and continually improve its effectiveness, and
- To enhance customer satisfaction by meeting requirements.

6.2 Human Resource

6.2.1 General

Management of Lactonova Nutripharm Private Limited ensures Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience.
6.2.2 Competence, awareness and training

Concerned Functional Heads ascertain the need for providing awareness and training in the identified area.

- Provide training and take other actions to satisfy these needs.
- Evaluate the training effectiveness of the action taken.
- Ensures that all the persons are aware of the relevance and importance of their activities and their contribution to achieve the defined Food safety objectives.
- Ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety
- Relevant records shall be maintained.

The training for new recruitment/existing employees is carried as per the defined procedure for training.

6.3 Infrastructure

Management provides necessary infrastructure needed to achieve conformity to product requirements. Infrastructure includes, for example,

a. Buildings, workspace and associated utilities
b. Process equipment, both hardware and software, and
c. Supporting services such as communication etc.

6.4 Work environment

All functional heads jointly review with the MD during MRM to analyze and review the present and future requirements with regard to the work environment and to manage the work environment needed to achieve conformity to product requirements. Director ensures that this review is conducted at least once a quarterly and that needs are fulfilled to the possible extent considering their implications on financial status and other business facets.

7. PLANNING AND REALIZATION OF SAFE PRODUCTS

7.1 Planning and realization of safe products

Lactonova Nutripharm Private Limited during the process of delivering quality and safe product to customer ensures that the planning and manufacturing processes needed for the product realization is carried out prior to the start of production maintaining the consistency with the requirements of the other processes of the Management System. This includes PRP(s) as well as operational PRP(s) and HACCP Plan.
During the planning of product realization, Lactonova Nutripharm Private Limited determines:

1) the Objectives and requirements appropriate for the product
2) the need to establish any additional or new processes, adequacy of applicable documents and provision of any identified resources specific to the product
3) Identification and development of measurement systems;
4) Validation of samples through experts
5) the required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for accepting the extent of quality and safety of the product.

7.2 Prerequisite Programmes [PRPs]

7.2.1 The QA Manager shall establish, implement and maintain PRP(s) to assist in controlling:

a) Lactonova Nutripharm Private Limited introducing food safety hazards to product through the work environment
b) Biological, Chemical and Physical contamination of the product(s), including cross contamination between products, and
c) Food safety hazard levels in the product and product processing environment

7.2.2 The PRP

i. The size and type of operation and the nature of the products being manufactured.
ii implemented across the entire production system, either as programmes applicable in general or as programmes applicable to particular product or operational line approved by the food safety team

7.2.3 Lactonova Nutripharm Private Limited shall consider the following when establishing these programmes.

a) Construction and layout of buildings and associated utilities,
b) Lay out Premises, including workspace and employee facilities
c) Supplies of air, water, energy and other utilities
d) Supporting services, including waste and sewage disposal
e) The suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance
f) purchased materials (raw material, ingredients, chemicals and packaging), supplies (water, air), disposals (waste and sewage) and handling of products (storage and transportation)
g) Measures for the prevention of cross contamination
f) Cleaning and sanitizing
h) Pest control
i) Personal Hygiene and other aspects as appropriate

Note: Records of verification and modifications shall be maintained.

7.3 Preliminary steps to enable hazard analysis

7.3.1 General

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.

7.3.2 Food safety team

The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system.

7.3.3 Product characteristics

7.3.3.1 Raw material, ingredients, product – contact materials and End product

Food safety team needed to conduct hazard analysis

a) Biological, Chemical and Physical Characteristics
b) Composition of formulated ingredients, including additives and processing aids
c) Origin
d) Method of production
e) Packing and delivery methods
f) Storage conditions and self life
g) Preparation and / handling before use or processing
h) Food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.
i) Labeling related food safety
j) Method of distribution
Lactonova Nutripharm Private Limited shall identify statutory and regulatory food safety requirement related to above.

7.3.4 Intended use

The reasonable expected handling of end product, and any unintended but reasonably expected mishandling and misuse of end product shall be considered in documents to the extent needed to conduct the hazard analysis.

7.3.5 Flow diagrams, Process steps and control measures

7.3.5.1 Flow diagrams

Lactonova Nutripharm Private Limited has made available a complete and actual description of the operation in the form of flow diagrams (process steps), which are included in Food Safety Manual for the Flow Diagram, and layouts (production facilities), which are available with the FST Leader. When applying ISO 22000 to a given operation, consideration is given to steps preceding and following the specified operation, which is evidenced in the flow diagrams and Hazard Identification & Risk Analysis worksheet. These descriptions are drawn up and verified by the Food Safety and Validation Teams.

The Flow Diagrams provide a schematic overview of the operation, and describe all the steps in sufficient detail to provide the Food Safety Team with adequate information for the ISO 22000. They take into account all relevant process steps, such as the manufacturing of the product, including critical points like:

- Approval of materials
- Pre-preparation
- Processing
- Dispatching

All facilities which are part of the infrastructure of Lactonova Nutripharm Private Limited, such as the production lines, storage areas and personnel facilities are depicted in layout plans. In the layout plans, the following items have been indicated:

- The routing of material, personnel. This is shown in the PLANT Layout.
- The areas and facilities for personnel use. This is shown in the PLANT Layout.

7.3.5.2 Description of process steps and control measures
The existing control measures, process parameters and shall described to the extent needed to conduct the hazard analysis.

Prior to the execution of changes in the production process and layout that could adversely affect food safety, these changes are reported to the Food Safety Team in order to evaluate potential hazards to food safety, and take preventive actions accordingly. Prospective changes are reported to Food Safety Team as per the Documentation Control Procedure and its supporting documents.

7.4 HAZARD ANALYSIS

7.4.1 General: The food safety team shall conduct hazard analysis to determine which hazards need to be controlled.

7.4.2 Hazard identification and determination of acceptable levels

Assessment:

Assessment is carried out in the organization on the basis of the food safety interference sources affecting the processes. The food safety interference sources considered are listed out as follows:

<table>
<thead>
<tr>
<th>Food Safety Interference Sources</th>
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<tbody>
<tr>
<td><strong>Process</strong></td>
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<tr>
<td>Machinery – wear &amp; tear / leakage points /</td>
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<tr>
<td>Food Contact Materials – surface contamination of the product</td>
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<tr>
<td>Environment – external or process environment</td>
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<tr>
<td>In Process Delay – time delay</td>
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<tr>
<td><strong>Food Contact Surfaces</strong></td>
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<tr>
<td>– Vessels or areas where product is processed</td>
</tr>
<tr>
<td><strong>Food handlers</strong> – Persons handling food processing coming in the scope of the organization</td>
</tr>
<tr>
<td><strong>System</strong> – any methodology to be followed / any factor to be monitored</td>
</tr>
<tr>
<td><strong>Food Harbourage</strong> – potential hazard that the food harbours in itself.</td>
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</tbody>
</table>

Based on the food safety interference sources, each process coming under the scope of the organization is assessed for any potential hazard posed from the food safety interference sources. This is separately documented in the HACCP plan assessment review.
**Listing out the Hazard:**
After assessing, the hazards are listed out basically as three categories – Physical, Biological and Chemical and are documented in the **hazard list.**

**Significant rating of hazard**

**Critical Control Points:**
For the entire identified hazard, the Critical Control Point is decided based on the decision tree and the rating system.

**General Control Measure:**
General control measure is identified based on the following factors.
- Specifications developed for acceptance of raw material, in process material and finished product
- Instructions developed for Process control
- Procedures developed
- Hygiene plan
- Sanitation plan
- Training plan

**Specific Control Measure:**
Specific control measures are identified based on the physical / chemical parameter such as temperature, time, pH, Visual appearance etc.

**Monitoring and measurement of product**

**Incoming Inspection**
Incoming Inspection is carried out as per **Incoming Inspection Plan** and recorded in **raw material Register** and **test Certificate** is received from the Suppliers

**In process and Final Inspection**
Products in the in process stages are controlled thro effective monitoring of manufacturing process parameters as per the relevant work instructions. The final inspections are carried out as per the **Final Inspection Plan** and recorded in **Analysis report of Finished Goods.** When required by customers, it is submitted to them.
Monitoring and Control of CCP

After determining the CCP, the preventive and corrective actions are identified and documented for each CCP. Control measures, Monitoring frequency, monitoring method, and monitoring responsibility for each CCP are defined in the HACCP plan. Concerned responsible person monitors the CCP and makes the report with his signature. The reports are reviewed and approved Director.

**Responsibility:** Core Team

7.5 Establishing the operational Prerequisite Programmes [PRPs]

The operational PRPs shall be documented and shall include the following information for each programme.

a) Food safety hazard (s) to be controlled by the programme (see 7.4)

b) Control measure (s) (see 7.4)

c) Monitoring procedures that demonstrate that the operational PRPs are implemented

d) Corrections and corrective action to be taken if monitoring shows that the operational PRPs are not in control

e) Responsibilities and authorities

f) Record(s) monitoring.

7.6 Establishing the HACCP Plan

7.6.1 HACCP plan

The HACCP plan shall be documented and shall include the following information for each identified critical control point (CPP).

a) Food safety hazard (s) to be controlled at the CCP

b) Control measures

c) Critical limits

d) Monitoring Procedure

e) Corrections and corrective action (s) to be take if critical limits are exceeded

f) Responsibilities and authorities.

g) Record(s) monitoring
7.6.2 Identification of critical control points (CCPs)
Each hazard that is to be controlled by the HACCP Plan, CCP(s) shall identified for the control measures identified.

7.6.3 Determination of critical limits for critical control points
a. critical limits established to ensure that the Identified acceptable level of the food safety hazard in the end product
b. Critical limits shall be measurable

d. monitoring frequency
e. responsibility and authority related to monitoring and evaluation of monitoring results.
f. record requirements and methods.

7.6.5 Actions when monitoring results exceed critical limits
Planned corrections and corrective actions to be taken when critical limits are exceeded as specified in the HACCP Plan. The actions shall ensure that the cause
Non conformity is identified, that the parameter(s) controlled at the CPP is brought back under control and that recurrence is prevented (see 7.10.2)

7.7 Updating Preliminary information and documents specifying the PRPs and the HACCP Plan:
The Lactonova Nutripharm Private Limited shall update the following information, if necessary
a) Product characteristics
b) Intended use
c) Flow diagrams
d) Process steps
e) Control measures
Note: If necessary, The HACCP Plan and the procedures and instructions specifying the PRP shall be amended.
7.8 Verification Planning
The verification activities shall conform that
a) The PRP(s) are implemented
b) Input the hazard analysis is continually updated
c) The operational PRP(s) and the elements within the HACCP plan are implemented and effective.

7.9 Traceability System
Lactonova Nutripharm Private Limited ensures that Identification and traceability of the product for its status with respect to monitoring and measurement requirements with appropriate unique system based on the customer requirements also.
Lactonova Nutripharm Private Limited has implemented tags/quarantine areas to identify different status of the product.
Lactonova Nutripharm Private Limited provided unique test code system for controlling all Products/records required for traceability wherever required.
The Products are dispatched to end distribution warehouse, who shall maintain the distribution records at their end. The products are dispatched by road, sea shipment or by air route as per logistics requirements. Product distribution is the responsibility of our customers/product owners/contract givers.

7.10 Control of nonconformity
7.10.1 Corrections
Lactonova Nutripharm Private Limited ensures that when critical limits for CCP(s) are exceeded, or there is loss of operational PRP(s), product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The control and related responsibility and authority for dealing nonconforming products at relevant stages is as per as the Procedure for Control of Nonconforming Products.
Lactonova Nutripharm Private Limited deals with nonconforming products by one or more of the following ways:
- By taking action to eliminate the detected nonconformity
By authorizing its use, release or acceptance under concession by a relevant authority and if required by the customer

- By taking action to preclude its original intended use or application.

Respective In charges maintain the records of nonconforming products and subsequent actions taken including concessions obtained, re inspection, re verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, Lactonova Nutripharm Private Limited takes action appropriate to the effects, or potential effects of the nonconformity.

### 7.10.2 Corrective Actions

All In charges take action to eliminate the cause of nonconformity in order to prevent recurrence. They ensure that corrective actions taken are appropriate to the effects of the nonconformities encountered.

Procedure for corrective and preventive action FSP-10 defines requirements for

a) Reviewing nonconformities (including customer complaints)
b) Determining the causes of nonconformities,
c) Evaluating the need for action to ensure that nonconformities do not recur,
d) Determining and implementing action needed,
e) Records of the results of action taken, and
f) Reviewing corrective action taken.

### 7.10.3 Handling of potentially unsafe products

#### 7.10.3.1 General

The Lactonova Nutripharm Private Limited shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that

a. The food safety hazard(s) of concern has been reduced to the defined acceptable levels.
b. The food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering into the food chain, or
c. The product still meets the defined acceptable level(s) of concern despite the non-conformity.
7.10.3.2 Evaluation for release
The product affected by the non conformance shall only be released when any of the following conditions apply:

a. Evidence other than the monitoring system demonstrates that the control measures have been effective.

b. Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (identified acceptable levels)

c. The results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

7.10.3.3 Disposition of nonconforming products
If the product is not acceptable for release it shall be handled by one the following Activities.

a) Reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels.

b) Destruction and/or disposal as waste

7.10.4 Withdrawals
a) Top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsibility for executing withdrawal

b) The Lactonova Nutripharm Private Limited shall establish and maintain a documented procedure for

i. Notification to relevant interested parties like statutory and regulatory authorities, customer and consumers.

ii. Handling of withdrawn products as well as affected lots of the products still in stock and the sequence of action to be taken.

8. VALIDATION, VERIFICATION AND IMPROVEMENT OF THE FOOD SAFETY MANAGEMENT SYSTEM.

8.1 General
The Food safety Team shall plan and implement the process needed to validate control measures and to verify and improve the food safety management system.
8.2 Validation of Control Measure combinations

The Lactonova Nutripharm Private Limited shall validate that

i. The selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated and

ii. The control measures are effective and capable of in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels.

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and modified and re assessed.

8.3 Control of monitoring and measuring

Maintenance In charge shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determine requirements. Concerned personnel’s shall ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment’s shall

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to International or National measurement standard

b) Be adjusted or re-adjusted as necessary.

c) Be identified to enable the calibration status to be determined.

d) Be safeguarded from adjustments that would invalidate the measurement.

e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, they shall record the validity of the previous measuring results when the equipment is found not to conform to requirements and take appropriate action on the equipment not to affect the product. The records of calibration and verification shall be maintained.

8.4 Food safety management system verification

8.4.1 Internal audit

Lactonova Nutripharm Private Limited plans and conduct internal audits every 3 months intervals to determine whether the FSMS

- Conforms to the planned arrangements, to the requirements of the standards and FSMS requirements established by Lactonova Nutripharm Private Limited.
- Effectively implemented and maintained.
Management Representative plans for the audits considering the status and the importance of the processes and areas to be audited, as well as the previous audit results.

The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

*Auditors shall not audit their own work.*

The responsibility and requirements for planning, conducting audits, reporting results and maintaining records shall be as per the procedure for Internal Audit.

**8.4.2 Evaluation of individual verification results**

The food safety team systematically evaluates the individual results of planned verification.

a. Existing procedure and communication channels.

b. The conclusion of hazard analysis the established operational PRP(s) and the HACCP plan

c. The PRP(s) and the effectiveness of human resource management and of training activities.

**8.4.3 Analysis of results of Verification activities**

The food safety team shall analyses the results of verification activities, including the results of internal audit and External audits. The analysis shall be carried out in order conform that the overall performance of the system meets the planned arrangements and the food safety management system requirements established by the Lactonova Nutripharm Private Limited, to identify the need for updating or improving the food safety management system, to identify the trends indicate a higher incidence of potentially unsafe products, to establish information for planning the internal audit programme concerning in the status and importance of areas to audited and to provide evidence that any corrections and corrective actions that have been taken are effective.

**8.5 Improvement**

**8.5.1 Continual Improvement**

Lactonova Nutripharm Private Limited is committed to continually improve the effectiveness of the Food Safety Management System through the use of Food safety Policy, evaluation of individual verification results, analysis of results of verification activities, verification of control
measure combinations, corrective actions, food safety management system updating, audit results, analysis of data, corrective and preventive action and management review.

8.5.2 Food safety management system updating

Top management shall ensure that the food safety management system is continually updated. In order to achieve this, the food safety team shall evaluate the food safety management system planned interval.