NAME OF THE COMPANY

GMP/ PRP MANUAL

Production site:

Address

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AMENDMENT RECORD SHEET

Issue No.01 Date 01.09.2022

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		Issue No	Rev.No.	Date	
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DEFINITIONS

Cleaning - The removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant - any biological or chemical agent, foreign matter, or other substances not Intentionally added to the production of product or the finished product which may compromise food safety or suitability.

Contamination - the introduction or occurrence of a contaminant during the rice bran oil production or at the finished product.

Disinfection - the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

Establishment - any building or area in which product is handled and the surroundings under the control of the same management.

Food hygiene - all conditions and measures necessary to ensure the safety and suitability of the final product at all stages of the production chain.

Hazard - a biological, chemical or physical agent present in the rice bran oil with the potential to cause an adverse health effect.

HACCP - a system which identifies, evaluates, and controls hazards which are significant for food safety.

Food safety - assurance that food will not cause harm to the consumer when it is prepared and/or

eaten according to its intended use.

Food suitability - assurance that food is acceptable for human consumption according to its intended use.

Primary production –Supplier audit.

Prerequisite program
Basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

Reference Documents

1. RECOMMENDED INTERNATIONAL CODE OF PRACTICE
GENERAL PRINCIPLES OF FOOD HYGIENE - CAC/RCP 1-1969, Rev. 5-2020

2. ISO/TS 22002-1:2009- PRP Food Manufacturing

Section 1

Supplier Audit Program

Purpose

To establish and maintain a procedure to monitor and periodically verify the suppliers/ vendors of the organization for adequacy in terms of their infrastructure and other facilities to ensure food safety.

Scope

This applies to all raw materials, ingredients, primary packing materials and other products procured by the company.

Responsibility

Quality Control.

Procedure

In order to ensure hygienic conditions at the manufacturing, storage and during the supply of the products to the company, periodic inspection/audit will be conducted using e.g. a supplier audit checklist.

The suppliers are intimated the specific requirements with respect to the food safety requirements such as:

- Controlling contaminants
- Pest control
- Adopting hygiene practices during production
- Environmental hygiene.
- Maintenance of hygiene during storage/transportation.
- Cleaning and maintenance.

The audit covers all aspects of food safety and associated elements of the organizational practices which has an impact on food safety. This includes aspects such as :

- Structure Size, Construction, and Design of the building.
- Certified Systems of the organization.
- Management Responsibility.
- Fundamentals of food hygiene.
- Food safety system.
- Manufacturing and quality system.
- Regulatory compliance.

The supplier audit will be conducted periodically (Yearly) and reports are maintained.

Reference

Nil

Records:

Supplier Audit Checklist

Section 2

Establishment: Design and Facilities:

Purpose:

To ensure that the facilities, surroundings, equipment and machinery will not pose any threat to food safety.

Scope:

This applies to the entire facility

Procedure

a) Establishment: The facility is located away from the environmentally polluting aspects such as:

- Industrial activities which pose a serious threat of contaminating the product;
- areas subject to flooding unless sufficient safeguards are provided;
- areas prone to infestations of pests;

The exterior of the facility is constructed and maintained to facilitate production to produce prime product that meets customers, statutory and food safety requirements.

Yards, grounds and roads which are in close proximity to the building are free from debris, garbage and adequately drained.

Building exteriors are designed and maintained to prevent contamination or entry of pests or contaminants.

b) Equipment's: The equipment used as part of the manufacturing process in the refinery section are of SS (Stainless steel) and it is adequate

- To maintenance and cleaning;
- functions in accordance with its intended use; and
- Facilitates good hygiene practices, including monitoring.

c) Premises and Rooms

The internal design and layout of the establishments permit adequate hygiene practices, including protection against cross-contamination between and during operations.

The structures within the establishments is soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected.

In particular the following specific conditions are satisfied where necessary to protect the safety and suitability of product:

• Floors are constructed to allow adequate cleaning;

• Ceilings and overhead fixtures are constructed to minimize the buildup of dirt and condensation, and the shedding of particles;

d) Water supply

Adequate supply of potable water with appropriate facilities for its storage and distribution are made available.

e) Personnel hygiene facilities and toilets

Employee facilities such as rest rooms, toilets is

- Adequate in size for maximum number of employees
- Readily accessible by the employees
- Physically separated from production area.

Personnel hygiene facilities are available to ensure that an appropriate degree of personal

Hygiene can be maintained and to avoid contaminating the product. The facilities include:

• Adequate means of hygienically designed hand wash facilities;

• Lavatories of appropriate hygienic design; and

• adequate changing facilities for personnel.

f) **Lighting**

Adequate natural or artificial lighting has to be provided to enable the undertaking to operate in a hygienic manner. The intensity is maintained adequately to the nature of the operation. Lighting fixtures are suitably protected to ensure that product is not contaminated by breakages.

Glass Policy

As a policy, the company does not allow any person to bring glass bottles, instruments or brittle plastic items inside the production area, product storage, logistic platform or packing area and has a documented glass policy and glass register.

Regular physical verification is conducted by supervisors . Any breakage of glass and plexi glass is reported immediately to the department head and proper actions are taken.

Equipment having glass and/or plexi glass in critical areas are made shatter proof were possible by e.g. using transparent sun film.

g) Storage

Adequate facilities for the storage of raw materials, additives, packing materials and chemicals (e.g. cleaning materials, lubricants, fuels etc are provided.

The storage facilities are designed and constructed to:

• permit adequate maintenance and cleaning;

• avoid pest access and harborage;

• enable the product to be effectively protected from contamination during storage.

Procedure for Stacking and storage

Raw Material.

The storage areas and the materials in the storage areas are kept clean, orderly and free from pest infestation.

Raw materials are preferably used on a first in first out basis (FIFO).

Packaging materials.

Packing materials are properly identified and stored in dry and clean areas.

Packaging materials are preferably used on a first in first out basis.

Finished products.

The products are packed in Tins –SS and BOPA pouches- (Food grade)and are stored in SS tanks to assure that there is no deterioration of the finished product.

The following aspects are of the at most importance:

- Ensure product is packed with the correct packing material.
- Ensure all products are labeled with the correct product label.
- Ensure all products are sealed correctly and are in sound physical condition.
- Maintain adequate space between the rows of stored products for cleaning, monitoring, and inspection.
- An inventory management system has to be implemented.
- Finished product should preferably picked on a first in first out basis.

Chemical control program

All chemicals used for maintenance, sanitation or pest control are stored in areas away from finished products, packing materials, processing equipment and ingredients.
The chemical storage area is secured with access restricted to authorized personal.

Material Safety data Sheet (MSDS) is maintained for all chemicals used in the facility.
All persons handling chemicals are trained in chemical control measures, and safety.

Lubricants are stored properly and identified. Food grade lubricants are stored separately from the non-food grade lubricants.

Pest control chemicals are stored properly and identified. These are stored at a location with limited access.

Cleaning chemicals are stored properly and identified. These are stored at a location with limited access.

Laboratory chemicals are stored in a dedicated area.

Reference :

Record:

Stock register raw materials and laboratory chemicals.

Stock Register Finished products.

Section 3

CONTROL OF OPERATION

Physical and chemical contamination

Systems has been established to prevent contamination of product by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices are used where necessary.

Maintenance program is in place and it includes the following aspects;

- Established a documented preventive maintenance program covering all the equipment's and facilities.
- Temporary repairs are made consistent with GMP practices using appropriate materials.
- Nonfood grade items such as wire, tapes, strings, plastic etc are not to be used for temporary repairs in the processing areas.
- It is ensured that cleaning and sanitation is done after maintenance activities, wherever applicable.

Product specifications:

The specifications for raw materials, ingredients and packing materials are documented and established (microbiological, chemical or physical parameters).These specifications are based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and specifications are defined.

INCOMING MATERIAL REQUIREMENTS

No raw material or packaging materials will be accepted if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal processing.

Where appropriate, specifications for raw materials are identified and applied.

Raw materials and packaging materials, where appropriate, will be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use.

Wherever required the raw materials are accompanied by certificate of analysis (CoA) or certificates of compliance (CoC) from the supplier.

Only sound and suitable raw materials and packaging materials are used.

Stocks of raw materials and packaging materials will be subject to effective stock rotation.

PACKAGING MATERIALS

Packaging materials (Primary packing materials) used are non-toxic and food grade and not pose a threat to the safety and suitability of the final product. These articles are preserved under the specified conditions of storage and use.

MANAGEMENT AND SUPERVISION

Managers and supervisors are having enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective actions, and ensure that effective monitoring and supervision takes place.

PRODUCT RECALL/ WITHDRAWAL PROCEDURES

Withdrawal: The removal of an unsafe food from the market before it has reached the consumer.

Recall: The removal of an unsafe food from the market when it may have reached the consumer and the notification of the consumer.

Purpose:

a) To establish a procedure to recall/withdrawal the products from the market to protect public health and interests by facilitating the efficient, rapid identification and removal of unsafe products from the market and where necessary, consumers and; to inform the competent authorities, other interested parties and the consumer, as appropriate.

b)Testing the effectiveness of the program periodically by mock recall.

Scope

This applies to all the products supplied to the customers including, products dispatched to clients, products on transit.

Responsibility

The Plant Manager and the Quality Officer are the authorized persons to implement and maintain the procedure.

Procedure

Type of situations

1. A situation in which there is a reasonable probability that the use of the product will cause serious adverse health consequences or death.
2. A situation in which the use of the product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote. (Illness); e.g. food poisoning.

When to Recall

The need for a recall can be established in a number of ways.

Some of the most common ways are:

- Report from customers.
- Internal information.

Recall Team Members

The Recall team consists of the people from the following areas of the company

Name	Designation	Dept.	Direct Phone

These departments may be represented by one or more people depending on the need of the situation.

The responsibilities of the team are to:

• Develop the companies recall/withdrawal plan.

• Managing the testing and adjustment of the plan.

• Regularly updating the plan.

• Managing the company's product incidents.

• Recommend changes in the operating procedures used by the company that will reduce the possibility of having to remove food from the market.

Recall coordinator

A recall coordinator is appointed by senior management to lead the food incident team. The recall coordinator will be knowledgeable about every aspect of the company 's operations and is responsible for the activities of the incident team.

The person will be delegated responsibility by senior managers to make decisions concerning the food recall/withdrawal procedure.

Contacts list

An updated contact list is maintained indicating the responsibilities in the food recall/withdrawal plan and are split into five sections as follows:

• Recall team and senior management (incl. key personnel if not part of the recall team).

• Suppliers of ALL raw materials and primary packaging.

• Distribution company and business customers.

• Sources of technical advice and support including laboratory facilities.

• Competent authorities.

The contact lists is comprehensive and it includes out of hours contact details. This will be kept as an integral part of the recall/withdrawal plan to facilitate fast and efficient information recovery.

Notification procedures

Obligations to notify interested parties can be summarized as follows:

• Unsafe product has reached consumers:

– Competent authorities

– Affected food businesses as applicable:

• Suppliers

• Distributors

• Agents

• Customers

Managing a product Recall

Managing a product recall/withdrawal by the company should be led by asingle individual, usually the Recall coordinator and the process should be managed by the recall team in accordance with the recall/withdrawal plan.

Managing a product recall/withdrawal follows a clear sequence of events:

- Identify the concerned
- Assemble the recall team
- Notify your applicable regulatory agencies
- Identify all products to be recalled
- Segregate (put on hold) affected products that are in your control
- Prepare a distribution list
- Prepare a press release (if necessary)
- Notify customers (informing them what to do with the recall products)
- Control recalled products and decide what to do with them
- Dispose of recalled products
- Review the product recall

The recalled products will be kept separately and identified asnon conforming product in an area clearly identified as '**RECALLED PRODUCT AREA'.**

Enter detailed information in the Recalled product Register.

Mark recalled product "Do Not Use" and "Do Not Discard." Inform the entire staff not to use the product.

The recalled products are kept at the designated location and the products are used or destroyed after verification and all details are recorded in the non-conformance product register.

Mock Recall

The purpose of a mock recall is to determine how quickly and thoroughly all records can be obtained and to evaluate the ability to accurately locate the product. In this recall /retrieval management it is essential to recover finished product.

Responsibility for conducting recall – Plant Manager

Frequency - yearly

Mock Recall Procedure

Choose a Batch number. From the delivery records determine the quantity dispatched and the actual stock.

Record this information on the Mock Recall Form

Note time that Mock Recall starts.

Record trace (tracking of recalled product) results. Calculate the percent completeness of traceability. If the result is <100% the root cause must be determined by the Recall Team.

When corrective actions are completed, the Recall Coordinator can sign off the form. Indicate the start and finish time on the form.

If an actual Withdrawal or Recall has occurred during the time that a mock recall/withdrawal is scheduled, the results of the actual Withdrawal or Recall can be used instead of performing a mock Withdrawal/Recall.

5.0 Reference

Procedure for control of records

6.0 Records

Product Recall record

Mock Recall record

Section 4

MAINTENANCE AND SANITATION

Purpose

To establish effective systems to ensure adequate and appropriate maintenance and cleaning of the facility to ensure;

− the control of pests;

− waste management; and

− monitor effectiveness of maintenance and sanitation procedures.

Scope :

This applies to the entire facility

Responsibility:

1. **Cleaning procedures and methods**

All the facility is cleaned by suitable cleaning methods or sanitation to ensure the safety of the product.

Cleaning schedules will be maintained and implemented per department cleaning schedule.

Areas included are but not limited:

- Operational areas (Floor, wall, drains, overheads)
- Equipment
- Warehouse
- Storage
- Maintenance
- Employee facilities
- Other plant areas.

Cleaning of machines & utilities.

The machines and other facilities used as part of the production, storage and handling of the products are cleaned as defined in the cleaning schedules.

Cleaning schedules should cover min. the following topics:

- Facility/Area to be cleaned
- Cleaning method
- Frequency of cleaning
- Tools
- Registration & remarks.
- Min. weekly monitoring by supervision
- Min. quarterly verification.

The records of cleaning and sanitation is maintained.

MONITORING EFFECTIVENESS

Sanitation systems will be monitored for effectiveness and periodically verified by microbiological SWAB tests.

Registrations of these monitoring and verification activities will be recorded.

Records:

Cleaning Schedule

Cleaning/ sanitation Records, incl. monitoring and verification.

2. PEST CONTROL SYSTEMS

Pests can be of a threat to the safety and suitability of our product. Pest infestations can occur where there are breeding sites. Good hygiene practices are employed to avoid creating an environment conducive to pests.
Documented procedure is established for pest control which includes the following aspects:

PURPOSE:

The Purpose of this document is to establish internal procedures for the identification of pest management areas and evaluation of procedures involved.

SCOPE:

This applies to the entire factory including its premises

Responsibility

Ware house in charge

Procedure

Preventing access

Buildings are kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access are kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Factory personnel have the day to day responsibility of ensuring that the pest management program remains operational and effective.

Information posters

In addition to training sessions the signage's are posted for information at individual workstations or sensitive locations such as rest areas and goods-inwards doorways are done as a reminder of the requirements of the Pest Management Program.

These will remind staff of pest related risks and preventive measures such as:

- Door and window disciplines
- Hygiene and housekeeping
- Stock storage and rotation

Monitoring Hot Spots

Threats to product safety exist both indoors and outdoors and it is essential for facility managers to monitor the facility's pest hot spots: areas where conditions conducive to infestation are commonly found, there are general areas of any structure that require special attention to ensure a pest-free environment.

Waste Storage: The most common outdoor hotspots develop in dumpster areas due to improper garbage storage and disposal, as inadequate waste management systems are often overlooked.

Entrance and Exit Points: It is easy for employees to mistakenly leave doors open, inviting pests to enter the facility.

Outdoor Lighting Fixtures: Proper outdoor lighting is important because pests are attracted to light.

Records

Pest Sighting log

Bait station Map

Section 5

PERSONAL HYGIENE

Purpose

To establish a procedure to ensure that those who come directly or indirectly into contact with the product are not likely to contaminate the product by:

− maintaining an appropriate degree of personal cleanliness;

− behaving and operating in an appropriate manner.

Scope

This applies to all personnel, incl. contractors, having access to the products handled by the company.

Responsibility

All personnel enters the facility who are likely to directly or indirectly come in contact with the product.

Procedure

Plant employees follow strict personal hygiene practices which include the following :

- A written dress code for all employees (new and part time), visitors and contractors. Employees wear clean clothing and shoes appropriate for the working condition.
- Wearing hair net in the packing area.
- No nail polish, jewelry, rings, watches etc.

HEALTH STATUSOF EMPLOYEES:

Periodical medical check-up.(once in year)

Injuries have to be treated properly via first aid .

Employees should maintain a high degree of personal cleanliness.

Personnel should always wash their hands when personal cleanliness may affect product safety, for example:

• at the start of product handling activities where there is direct contact with the finished product;

• immediately after using the toilet; and

• after handling raw materials or any other materials, where this could result in the contamination of the finished product.

- Consumption of food and beverages is only allowed in the canteens and offices.

POST SICK LEAVE CHECK-UP:

All the employees returning from sick leave shall be ascertained for employee's physical fitness.

Hygiene aspects

- All cuts and wounds will be covered with a medicated strip.
- Hair should be clean and properly maintained.

FOOD HYGIENE GOLDEN RULES

- ALWAYS wash your hands after eating and toilet visits.
- REPORT for any skin, nose, throat, or bowel trouble.
- ENSURE cuts and sores are properly covered.
- KEEP yourself clean and wear clean clothing.
- DO NOT SMOKE in any operational area. Smoking is only allowed in the dedicated places.
- CLEAN as you go. Keep all equipment and surface clean.
- ENSURE waste food is disposed off properly.

FREQUENCY:

1. Before starting work
2. In between different jobs
3. After handling raw material
4. After handling garbage & soiled material
5. After handling dirty equipment's & utensils
6. After sneezing onto hands accidentally
7. After touching body parts (e.g. fingering of nose)
8. After & before eating or drinking
9. After using the toilet
10. After finishing the days work

UNIFORMS HYGIENE

- All the employees are provided with suitable clean and appropriate uniform while on duty especially in the packaging area.
- Laboratory personnel have blue lab coats.

PERSONAL BEHAVIOUR

People engaged in handling finished product should refrain from behavior which could result in product contamination, for example:

- smoking;
- spitting;
- chewing or eating;
- sneezing or coughing.

VISITORS

Visitors to manufacturing, processing or handling areas is restricted as a policy, however the entry of the visitor to the manufacturing, processing and finished product handling areas will be guided by hygiene rules as given below:

Visitors to manufacturing area's are required to follow the dress code and also the laid down requirements as defined in the hygiene rules/policy.

The visitors and non-establishment workers are restricted from entering the processing area unless if accompanied by an authorized staff.

A copy of the visitor's code is available in the security and at the front office.

5.0 Reference

6.0 Records

Medical certificates

Personal hygiene Checklist

Visitor Declaration form

Section 6

TRANSPORTATION

Objective :

To establish a procedure to :

− protect product from potential sources of contamination;

− protect product from damage likely to render the product unsuitable for use.

Scope :

This applies to all products transported from the factory to various locations and products received by the factory from suppliers.

Responsivity:

Executive Director

Transporter.

Procedure:

The tanker inspection (including bulk carriers) criteria has been laid down which include the following aspects:

- Acceptable and unacceptable conditions of the goods

- Whether clean and intact
- Free from moisture and offensive odors
- Free from pest, chemicals, glass etc.

Bulk crude oil receiving and shipping are kept secure, clean and stored in sanitary manner.

Transportation of products:

1. The tankers are engaged and checked for its adequacy based on checklist . No special temperature and humidity conditions are required for transportation of the product.
2. Conveyances and bulk containers are designed and constructed so that they do not contaminate or damaged the the finished product.
3. Transporting vehicles will be effectively cleaned, repaired and, where necessary, disinfected.
4. A vehicle hygene checklist is maintained to ensure the hygienic condition of the vehicle.

5. Reference

Nil

6. Records

Vehicle hygiene check list

Section 7

PRODUCT INFORMATION AND CONSUMER AWARENESS

Objective:

To establish a procedure to provide appropriate information to the user to ensure that:

− adequate and accessible information is available to the customer to enable them to handle, store, process, prepare and display the product safely and correctly;

− the lot or batch can be easily identified and recalled if necessary.

Consumers should have enough knowledge of food hygiene to enable them to:

− understand the importance of product information;

− make informed choices appropriate to the individual; and

− prevent contamination by storing, and using it correctly.

Scope :

This applies to oil/DOB supplied to the customers.

Responsibility:

Labeling/ Marketing Department

Procedure:

LOT IDENTIFICATION

All the pouches/ Tins and Tankers are identified by Batch number to enable traceability, recall and also helps effective stock rotation.

PRODUCT INFORMATION & LABELLING

All the products will be accompanied by or bear adequate information to enable the customer to handle, display, store and use the product safely and correctly. Detailed product information is given along with the product and each tin/pouch is externally identified for its batch number and product identification.

The labeling of the product is in compliance with FSSA requirements/ or export requirements.

Product Identification and Traceability

PURPOSE:

To lay down a procedure to specify a means of product identification at all stages from receipt, production and delivery including the product status. Enabling traceability of the product in the food chain.

SCOPE:

This applies to identification and traceability of purchased raw materials, additives, finished products and packing materials.

RESPONSIBILITY:

Identification: warehouse & production.

Traceability: food safety team.

PROCEDURE

At all stages of handling the raw materials and packaging materials are identified by batch and or lot numbers/code.

At the end of each inspection and testing, the inspection and test status is provided as per documented procedure.

Traceability is established from raw material to finished product for all batches and batch records are maintained.

Any unidentified item located in store/production shop is re-inspected/checked against the specification to ensure correct identification.

Effectiveness of the procedure is being checked once in a year by conducting mock traceability test stream upwards and downwards.

RECORDS:

Mock traceability Record.

Section 8

TRAINING

Purpose:

To provide sufficient information/ training to operators and other persons who come directly or indirectly into contact with finished product, with respect to food hygiene, to a level appropriate to their work performance.

Scope :

All personnel

Responsibility

HR/ QC Departments

Procedure

AWARENESS AND RESPONSIBILITIES

Product hygiene training is fundamentally important. All personnel must be aware of their role and responsibility in protecting the product from contamination or deterioration.

Persons should have the necessary knowledge and skills to enable them to handle product hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

TRAINING PROGRAMMES

Training plan is prepared based on the basic hygiene requirements of the finished product which will include:

- the nature of the product, in particular the hygiene requirements
- the manner in which the product is handled and packed, including the probability of contamination;
- the extent and nature of processing or further processing at the customers site;
- the conditions under which the product will be stored.
- Food safety (ISO 22000 Overview).
- Personal hygiene and GMP.

Training Records will be maintained indicating details of the program.

INSTRUCTION AND SUPERVISION

Periodic assessments of the effectiveness of training and instruction program will be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

Managers and supervisors of processes will have the necessary knowledge of product hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

Reference

Records

Training Plan.

Training Records.

Section 9

Food Defense, Bio vigilance and Bio terrorism

Documented procedure for food defense is established (Ref; Food Defense Procedure).