RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR GOOD MANUFACTURING PRACTICES FOR FOOD PRODUCTS

JANUARY, 2023

Doc. No.: FDISM/FDIC/GDL/004	Revision Date: 23/01/2023	Review Due Date: 30/01/2026
Revision No.: 1	Approval date: 25/01/2023	Effective Date: 31/01/2023

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body that was established by the Law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. One of its main powers is to formulate regulations and guidelines for regulating the manufacture of food products to ensure that they comply with quality standards required for good manufacturing practices.

The manufacture of food products is a basic philosophy which embraces many clearly defined principles; each of which combines certain specialized features and functions requiring constant attention and vigilance by qualified personnel.

Quality is a summation of the intangible factors necessary and sufficient to assure performance of desired functions. It cannot be tested into a product, but must be built into it by manufacturer in every phase of processing and production. The excellence of a company's product reflects the integrity, competence and pride of all those involved in the design, production and marketing of the products

One of the most well-known sets of requirements that have a major impact on the food industry is called Good Manufacturing Practices (GMP). These guidelines describe the minimum requirements that the Rwanda Food and Drugs Authority (Rwanda FDA) considers necessary for the production of food for human consumption. These guidelines address the requirements for premises, equipment, personnel, quality and process controls, documentation, storage, validations, and manufacturing processes including packaging and labelling.

These guidelines shall be considered as general guides and shall be adopted to meet individual needs, making sure that the established standards of quality for food are achieved.

This guideline shall be used to justify GMP status for manufacturing authorization of local facilities and as a prerequisite prior to registration of food products. It is my hope that this guideline will be useful to inspectors of the Rwanda Food and Drugs Authority (Rwanda FDA) during assessment of food manufacturing facility in compliance with GMP requirements. It is also hoped that the document will be useful for promotion of compliance to GMP for food manufacturing industries.

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	May 2019
ADOPTION BY RWANDA FDA	13/05/2019
STAKEHOLDERS CONSULTATION	25/08/2022
ADOPTION OF STAKEHOLDERS' COMMENTS	02/09/2022
DATE FOR COMING INTO EFFECT	31/01 /2023

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
May 2019	0	First Issue
23/01/2023	1	1. Scope and policy were added 2. The content of chapter 1, chapter 2 and chapter 3 were added. 3. The following annexes were added in the guideline a. Application for good manufacturing practice inspection for food product manufacturing facilities b. Requirements for GMP application for food manufacturing facilities c. Good Manufacturing Practices (GMP) inspection checklist d. Content of site master file e. Format of corrective and preventive action (CAPA) f. Content of Quality manual g. Format of the inspection report h. .Certificate of compliance with good manufacturing practice

TABLE OF CONTENTS

ACCRONYMES AND ABBREVIATIONS

GMP	Good Manufacturing Practices
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedures
CAPA	Corrective Actions and/or Preventive Actions
ISO	International Organization for Standardization
BRC	British Retail Consortium
FSSC	Food safety system certification scheme
HACCP	Hazard Analysis Critical Control Point

GLOSSARY / DEFINITIONS

In these guidelines, unless the context otherwise states:

"Authority" Means the Rwanda Food and Drugs Authority or its acronym Rwanda FDA.

"Batch "Means the quantity of material which has been produced during a defined period of manufacture. A "batch" may actually have been produced by a batch-wise process, or may correspond to the particular time duration during the run of a continuous process.

"Batch Number" Means a unique combination of numbers or letters, or both, used to identify a batch and permit its history to be traced.

"Competent authority" Means any person or organization that has the legally delegated or invested authority, capacity, or power to perform a food control regulatory function.

"Contract manufacture" Means the manufacture or partial manufacture ordered by one person or organization (the Contract Giver) and carried out by a separate person or organization (the Contract Acceptor).

"Critical Control Point (CCP)" Means a material, or a location, or a practice, or a procedure, or a process stage where loss of control would result in an unacceptable food safety risk.

"CIP" Cleaning In Place**.**

"COP" Cleaning Out of Place**.**

"Contamination" the action or state of making or being made impure by polluting or poisoning.

"Documentation" means written production procedures, instructions and records, quality control procedures, and recorded test results involved in the manufacture of a product.

"Durable construction" means the resistance to degradation of products, materials, buildings and other built assets over time.

"Finished Product" Means a product which has undergone all stages of manufacture and packaging.

"Food Allergen" Means a food substance which, in some sensitive individuals, causes an immune response causing bodily reactions resulting in the release of histamine and other substances in the tissues from the body's mast cells in the eyes, skin, respiratory system and intestinal system.

"Food Control" Means a mandatory regulatory activity of enforcement by National or local authorities to provide consumer protection and ensure that food during production, handling, storage, processing and distribution are safe, wholesome and fit for human consumption; conform to the quality and safety requirements; and are honestly and accurately represented in its labeling as prescribed by law.

"Frozen Foods" Means foods preserved by freezing and storing at temperatures, low enough to inhibit the growth of microorganisms and to retard chemical and physical reactions to a negligible rate**.**

"Good Manufacturing Practice" Means a combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications.

"Hazard Analysis Critical Control Point (HACCP)" Means a system which identifies, evaluates and controls hazards which are significant for food safety.

"Hazard" Means a biological, chemical or physical agent in, or condition of, food with a potential to cause an adverse health effect.

"Hazard Analysis" Means a process of collecting and evaluating information on the hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP Plan.

"Ingredients" Means all materials, including starting materials, processing aids, additives and compounded foods, which are included in the formulation of the product.

"Manufacture" Means a complete cycle of production of a food from the acquisition of all materials through all stages of subsequent processing, packaging and storage to the dispatch of the finished product.

"Packaging material" Means any container or material used in the packaging of a product. This may include materials in direct contact with the product, printed packs, including labels, carrying statutory and other information, and other packaging materials including outer cartons or delivery cases. These categories are, of course, not necessarily mutually exclusive.

"Processing" Means the transformation of raw ingredients into food, or of food into other forms.

"Quality Assurance" Means the total of the organized arrangements made with the objective of ensuring that finished products are of the quality required for their intended use.

"Quality Control" Means part of GMP that ensures raw materials are not released for use, and that finished product are not released for sale or supply, until their quality has been deemed satisfactory.

"Quality Management" Means a comprehensively designed and correctly implemented system of Quality Assurance (QA) that incorporates Good Manufacturing Practices (GMP) and Quality Control (QC).

"Quarantine" Means a process of setting aside any materials or product while awaiting a decision on its suitability for its intended use or sale.

"Raw Material" Means any material, ingredient, starting material, semi- prepared or intermediate material, packaging material, etc., used by the manufacturer for production of a product.

"Rework" Means unincorporated food product kept for subsequent use or reprocessing.

"Risk" Means the probability that a particular adverse consequence results from a hazard within a stated time under stated conditions.

"Specification" Means a document giving a description of material, machinery, equipment, process of product in terms of its required properties or performance.

"Potable water" water that is suitable for human consumption.

"Non-potable water" water that is not suitable for human consumption.

"SOP" means Standard Operating Procedure

"Unsafe product" means products which cause or may cause damages either by its manufacture defect; or its design defect; or by having no instruction, preservation, warning message, or relevant information about the product; or having incorrect or unclear information with regard to its nature including its usual usage and preservation.

1. INTRODUCTION

1.1. PURPOSE OF THESE GUIDELINES

1) Purpose of these guidelines

These guidelines are intended to provide guidance to the manufacturers of food products on how to comply with Good Manufacturing Practice (GMP).

2)The guidelines shall form the basis of GMP inspection by Rwanda Food and Drugs Authority (Rwanda FDA) as one of the requirements for registration of food products in Rwanda.

3)These guidelines were developed in accordance with Regulations Nº FDISM/FDIC/TRG/008 *Regulation governing good manufacturing practices of food products.*

1.2.SCOPE

These guidelines (and the Annexes) shall be used for GMP inspection of all manufacturers of food products within and outside Rwanda whose products are registered or subjected to registration in Rwanda; irrespective of their size, type of products, product range or location of the manufacturing facilities. Manufacturers that are GMP compliant shall be awarded certificates of compliance with GMP, in accordance with Article 23 of the Regulations Nº FDISM/FDIC/TRG/008

2. GOOD MANUFACTURING PRACTICE INSPECTION

2.1. Types of inspections

There are four types of Good Manufacturing Practice inspections divided into the following categories:

a. **Routine GMP inspection** is a full inspection of all applicable components of GMP and licensing provisions. It may be indicated when the manufacturer:

   i. Is newly established entity;
   ii. Requests for renewal of a manufacturing license;
   iii. Has a history on non-compliance with GMP;
   iv. Has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment;
   v. Has not been inspected during a period of the last 3 to 5 years.

b. **Concise GMP inspections** are the evaluation of limited aspects relating to GMP compliance within a facility. The manufacturers with a consistent record of compliance with GMP through previous routine inspections are eligible for concise inspections. The focus of a concise inspection is on a limited number of GMP requirements selected as indicators of overall GMP performance, plus the identification of any significant changes that could have been introduced since the last inspection. Collectively, the information obtained will indicate the overall attitude of the firm towards GMP. Evidence of unsatisfactory GMP performance observed during a concise inspection should trigger a more comprehensive inspection.

c. **Follow-up GMP inspections** may include reassessment or re-inspections made to monitor the result of corrective measures. They are normally carried out from 6 weeks to 6 months after the initial inspection, depending on the nature of the defects and the work to be undertaken. They are limited to specific GMP requirements that have not been observed or that have been inadequately implemented.

d. **Special GMP inspections** may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports of adverse drug reactions. Such inspections may be focused on one product, a group of related products, or specific operations such as mixing, sterilization, or labelling. Special visits may be also made to establish how a specific product is manufactured as a prerequisite for marketing approval or issuance of an export certificate.

These inspections can be conducted announced whereby the Authority shall notify the manufacturer to be inspected before conducting GMP inspection or announced in case of follow-up, suspicion, complaints or post market surveillance findings.

2.2. Application for GMP Inspection

A person interested in food processing should apply for good manufacturing practice inspection by submitting required documents as detailed below:

a. Filled and signed application form;
b. Proof of payment of prescribed fees;
c. Food safety prerequisites manual(FSPM);
d. License of premises for food product manufacturing;
e. List of all the products manufactured on site;
f. A copy of any warning letter or equivalent regulatory action issued by any authority to which the site provides or has applied to provide the product;
g. Corrective action and preventive action (CAPA) related to the GMP inspection report observations/non-compliances if any;
h. GMP inspection report issued by other competent authorities, if any;
i. Current GMP Certificate/ISO 22000/HACCP/FSSC 22000/BRC, etc. if any;
j. Product description including brief description of product validated formulation, product testing results and stability study report;
k. Self-inspection report;
l. Quality Manual/Laboratory Manual or equivalent;
m. The most recent batch records;
n. A list of any recalls or any Market complaints register in the last three years;
o. Contract or agreement between manufacturer and the outsourced testing laboratory (List of Subcontractor).

The application shall be made based on the following categories: New application, renew, variation and relocation.

However, incomplete applications that will be dormant for a period exceeding three (3) months shall be rejected, and the applicant shall be required to reapply, with prescribed fees applicable.

2.3. Methods of GMP inspection

The GMP inspection shall be conducted using one of the following method:

a. **Physical inspection:** Shall be conducted by physically visiting the manufacturing site. The applicant holding third party food safety certificate of compliance shall be evaluated by conducting site visit before issuing the GMP Certificate.
b. **Virtual**: Facilities for virtual/remote interactive inspections is conducted upon discretion of the Authority. The criteria of selection of applicants for virtual/remote interactive inspections shall be as follows:
    i. Authority has declared force majeure on physical inspection
    ii. Application that met requirements in 2.2. that still need further clarification.
c. **Joint Inspection:** The Authority may participate in the joint GMP inspection with regulatory Authorities from other countries such as East African Partner States and unless notified, this regulation shall apply.

2.4. Desk review and reliance

2.4.1. After receiving the application, the Authority may conduct an assessment of the application by desk review or use any other inspection report from a relevant regulatory body to satisfy itself that the application has complied with the conditions for good manufacturing practice.

2.4.2. The criteria to be used for documents desk review shall be as follows:

a. Applicant will be assessed under desk review when:
   i. holds food safety certificate such as ISO 22000/HACCP/FSSC 22000/BRC issued by accredited body.
   ii. holds food safety certificate issued by a competent National Regulatory Body that has Mutual recognition agreement with the Authority.
   iii. holds food safety certificate issued by competent National regulatory body from a stringent regulatory system.

b. If the applicant holds food safety certificate and is not from the country where the National Regulatory Body has Mutual recognition agreement with the Authority, the decision will depend on the evaluation of the scheme used by the Regulatory Authority in the country of origin.

3. AREAS OF GMP INSPECTION

A system for quality and food safety management shall be applied by all manufacturers to ensure the production of safe and suitable food at all stages of the food processing from reception of raw materials up to the final product.

3.1. Good hygiene practices

Manufacturers shall adopt practices and measures to ensure food is produced under appropriately hygienic conditions in order to reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at all stages of the food processing. Manufacturers shall ensure that the prerequisite programmes are fully established, implemented and maintained to assist in controlling food safety hazards. Prerequisite programmes are the basic conditions and activities that are necessary within the processing company to maintain food safety. When establishing the prerequisite programs, manufacturer shall consider:

3.1.1.Location of Premises

Food manufacturing premises shall be located in the designated industrial area. For unpredicted reasons, food manufacturing premises shall be located at least 100 meters away from residential area. Food premises should not be located where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of a premises, including temporary/mobile premises, should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, premises should normally be located away from:

a. Environmentally polluted areas and industrial activities which are reasonably likely to contaminate food;
b. Areas subject to flooding;
c. Areas prone to infestations of pests;
d. Areas where wastes, either solid or liquid, cannot be removed effectively.

3.1.2. Design and layout of food manufacturing premises

a. Buildings are of durable construction which presents no hazard to the product.
b. The design and layout of food premises shall permit adequate maintenance and cleaning.
c. The layout of premises and the flow of operations, including the movements of personnel and material within the buildings, shall be such that cross-contamination is minimized or prevented.
d. Areas having different levels of hygiene control (e.g. the raw material and finished product areas) shall be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, or separation in time, with suitable cleaning and disinfection between uses.
e. The building is adequately fenced to keep out larger animals such as dogs or cats.

3.1.3. Internal structures and fittings

Structures within food manufacturing premises shall

a. be soundly built of durable materials, which are easy to maintain, clean and, where appropriate, easy to disinfect
b. be constructed of non-toxic and inert materials according to intended use and normal operating conditions.

In particular, the following specific conditions shall be satisfied to protect the safety and suitability of food:

a. The surfaces of walls, partitions and floors shall be made of impervious materials that are easy to clean and, where necessary, disinfect;
b. Walls and partitions shall have a smooth surface up to a height appropriate to the operation;
c. Floors shall be made by smooth material free from cracks and joints to allow adequate drainage and cleaning;
d. Ceilings and overhead fixtures (e.g. lighting) shall be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles;
e. Windows shall be easy to clean, be constructed to minimize the build-up of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens;
f. Doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect.
g. Work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and to disinfectants under normal operating conditions.

3.1.4. Utilities: Air, Water and Energy

The provision and distribution routes for utilities to and around processing and storage areas shall be designed to minimize the risk of product contamination. Utilities' quality shall be monitored to minimize product contamination risk. Those include:

3.1.4.1. Air

Room air supply quality shall be controlled to minimize risk from airborne microbiological contamination. This include:

a. Where there is risk of food product contamination, the protocols for air quality monitoring and control shall be established;
b. Ventilation systems shall be designed and constructed such that air does not flow from contaminated or raw areas to clean areas;
c. Ventilation system shall ensure control of unwanted odours which might affect the suitability of food;
d. Specified air pressure differentials shall be maintained;
e. Ventilation systems shall be accessible for cleaning, filter changing and maintenance;
f. Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination;
g. Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be from a source approved for
    i. food contact use;
    ii. filtered to remove dust;
    iii. filtered to remove oil and water;
h. Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade. Alternatively, use of oil free compressors is recommended.

3.1.4.2. Water

The food manufacturing facility shall have the following:

a. Sufficient supply of potable water to meet the needs of the production process(es);
b. Appropriate storage for potable water and distribution system;
c. Water used as a product ingredient (including ice or steam) or in contact with products or product surfaces, shall meet specified quality and microbiological requirements relevant to the product;
d. Water quality (according to purpose of its use) complying with specifications for Portable, Purified Water or distilled water;
e. Water treatment system is effective and consists of carbon and sand filters, de-mineralisers, UV light/ozone systems (where applicable);
f. Water for cleaning or applications where there is a risk of indirect product contact (e.g. jacketed vessels, heat exchangers) shall meet specified quality and microbiological requirements relevant to the application;
g. Where water supplies are chlorinated, ozonation or any other chemical for disinfection, checks shall ensure that the residual level thereof at the point of use remains within limits given in relevant specifications;
h. Non-potable water shall have a separate supply system that is labelled and not connected to the potable water system. Measures shall be taken to prevent non-potable water refluxing into the potable system;
i. Water that comes into contact with the product shall flow through food grade pipes and the later shall be disinfected;

j. Water recirculated for reuse and water recovered from e.g. food processing operations, by evaporation and/or filtration shall be treated where necessary to ensure that the water does not compromise the safety and suitability of food.

3.1.4.3. Energy

a. Adequate natural or artificial lighting should be provided to enable the food production to operate in a hygienic manner. Lighting should be such that it does not adversely impact the ability to detect defects of, or contaminants in, food or the examination of facilities and equipment for cleanliness. The intensity should be adequate to the nature of the operation. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements.

b. All other sources of combustible materials in food processing and production shall not be a source of food contamination.

3.1.5. Waste disposal

Systems shall be in place to ensure that waste materials are identified, collected, removed and disposed of in a manner which prevents contamination of products or production areas.

3.1.5.1. Containers for waste and inedible or hazardous substances

Containers for waste and inedible or hazardous substances shall be:

a. clearly identified and labelled for their intended purpose;
b. located in a designated area;
c. constructed of impervious material which can be readily cleaned and sanitized;
d. closed when not in immediate use;
e. locked where the waste may pose a risk to the product.

3.1.5.2. Waste management and removal

a. Provision shall be made for the segregation, storage and removal of waste. Accumulation of waste shall not be allowed in food-handling or storage areas. Removal frequencies shall be managed to avoid accumulations, with a minimum daily removal;
b. At the facility level, there shall be a dedicated, labelled and locked area for temporarily storing of waste before final disposal;
c. Labelled materials, products or printed packaging designated as waste shall be disfigured or destroyed to ensure that trademarks cannot be reused. Removal and destruction shall be carried out by approved disposal contractors. The organization shall retain records of destruction.

3.1.5.3. Drains and drainage

a. Drains shall be designed, constructed and located so that the risk of contamination of materials or products is avoided;
b. Drains shall have capacity sufficient to remove expected flow loads;

c. Drains shall not pass over processing lines;
d. Drainage direction shall not flow from a contaminated area to a clean area.

3.1.6. Equipment suitability, cleaning and maintenance

Food contact equipment shall be designed and constructed to facilitate cleaning, disinfection and maintenance. Contact surfaces shall not affect, or be affected by the intended product or cleaning system. Food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

3.1.6.1. Hygienic design

Equipment shall meet established principles of hygienic design, including:

a. smooth, accessible, cleanable surfaces, self-draining in wet process areas;
b. use of materials compatible with intended products and cleaning or flushing agents;
c. framework not penetrated by holes or nuts and bolts.
d. piping and ductwork shall be cleanable, drainable, and with no dead ends
e. equipment shall be designed to minimize contact between the operator's hands and the products.

3.1.6.2. Product contact surfaces

Product contact surfaces shall be constructed from materials designed for food use. They shall be impermeable and rust or corrosion free.

3.1.6.3. Temperature control and monitoring equipment

a. Equipment used for thermal processes shall be able to meet the temperature gradient and holding conditions given in relevant product specifications.
b. Equipment shall provide for the monitoring and control of the temperature.

3.1.6.4. Cleaning plant, utensils and equipment

a. Wet and dry cleaning programmes shall be documented to ensure that all plant, utensils and equipment are cleaned at defined frequencies.
b. The programmes (SOP and records) shall specify what is to be cleaned (including drains), the responsibility, the method of cleaning (e.g. CIP, COP), the use of dedicated cleaning tools, removal or disassembly requirements and methods for verifying the effectiveness of the cleaning

3.1.6.5. Preventive and corrective maintenance

a. A preventive maintenance programme (SOP and records) shall be in place and include all devices used to monitor and/or control food safety hazards.
b. Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

c. Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.
d. The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection.
e. Maintenance personnel shall be trained in the product hazards associated with their activities.

3.1.7. Management of purchased materials

Purchasing of materials which impact food safety shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified purchase requirements shall be verified.

3.1.7.1. Selection and management of suppliers

There shall be a defined process for the selection, approval and monitoring of suppliers. Such selection shall be based on:

a. assessment of the supplier's ability to meet quality and food safety expectations, requirements and specifications;
b. visit of the supplying site prior to accepting materials for production;
c. appropriate third party certification.
d. monitoring the performance of the supplier to assure continued approval status. Monitoring includes conformity with material or product specifications, fulfilment of certificate of analysis requirements, satisfactory visit outcomes.

3.1.7.2. Incoming material requirements (raw/ingredients/packaging)

a. Delivery vehicles shall be checked prior to, and during, unloading to verify that the quality and safety of the material has been maintained during transit (e.g. integrity of seals, freedom from infestation, existence of temperature records, visual examination for packages damaged during transportation, use-by-date and declared allergens, or temperature measurement for refrigerated and frozen foods).
b. Materials shall be inspected, tested or supported by certificate of analysis to verify conformity with specified requirements prior to acceptance or use. The method of verification shall be documented. The inspection frequency and scope can be based on the hazard presented by the material and the risk assessment of the specific suppliers.
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. Access points to bulk material receiving lines shall be identified, capped and locked. Discharge shall take place only after approval and verification of the material to be received.

3.1.8 Source of cross contamination and their prevention

Procedures shall be in place to prevent, control and detect contamination. Measures to prevent physical, chemical and microbiological contamination shall be included.

3.1.8.1. Physical contamination

Under physical contamination, sources of potential contamination may include wooden pallets and tools, rubber seals, and personal protective clothing and equipment.

a. Where brittle materials are used, periodic inspection requirements and defined procedures in case of breakage shall be put in place. Brittle materials, such as glass and hard plastic components in equipment, should be avoided where possible. Glass breakage records shall be maintained.
b. Based on hazard assessment, measures shall be put in place to prevent, control or detect potential contamination. Examples of such measures include:
    i. adequate covers over equipment or containers for exposed materials or products;
    ii. use of screens, magnets, sieves or filters;
    iii. use of detection or rejection devices such as metal detectors or X-ray.

3.1.8.2. Chemical contamination

Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, lubricants, chemical residues from pesticides and veterinary drugs such as antibiotics. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives and food processing aids that may be harmful if used improperly including but not limited to overdosing should be controlled so they are only used as intended.

3.1.8.3. Microbiological cross-contamination

Systems should be in place to prevent or minimize contamination of foods by microorganisms. Microbiological contamination occurs through a number of mechanisms, including the transfer of microorganisms from one food to another, e.g.:

a. by direct contact or indirectly by food handlers;
b. by contact with surfaces;
c. from cleaning equipment;
d. by splashing; or
e. by airborne particles.

Raw, unprocessed food, where not considered ready-to-eat, which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and, where appropriate, effective disinfection.

Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a potentially high microbiological load such as meat, poultry, and fish have been handled or processed.

In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from that worn in other parts of the facility), including head and beard covering, footwear, and to wash their hands and where necessary sanitize them.

3.1.8.4 Food allergens management

Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives, should be identified in raw materials, other ingredients and products. A system of allergen management should be in place at receipt, during processing and storage to address the known allergens.

Allergens present in the product shall be declared. The declaration shall be on the label of final products, and on the label or the accompanying documentation for products intended for further processing.
Products shall be protected from unintended allergen cross-contact by cleaning and line change-over practices and/or product sequencing. Manufacturing cross-contact can arise from either:

a. traces of product from the previous production run which cannot be adequately cleaned from the product line due to technical limitations; or
b. when contact is likely to occur, in the normal manufacturing process, with products or ingredients that are produced on separate lines, or in the same or adjacent processing areas. Rework containing allergen(s) shall be used only:
   a) in products which contain the same allergen(s) by design; or
   b) through a process which is demonstrated to remove or destroy the allergenic material.

Employees handling food should receive specific training in allergen awareness and associated manufacturing practices.

3.1.9. Cleaning and sanitizing

Cleaning and sanitizing programmes shall be established to ensure that the food-processing equipment and environment are maintained in a hygienic condition. Programmes shall be monitored for continuing suitability and effectiveness.

3.1.9.1. Cleaning and sanitizing agents and tools

Facilities and equipment shall be maintained in a condition which facilitates wet or dry cleaning and/or sanitation.
Cleaning and sanitizing agents and chemicals shall be clearly identified, food grade, stored separately and used only in accordance with the manufacturer's instructions.
Tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter.

3.1.9.2. Cleaning and sanitizing programmes

Cleaning and sanitizing programmes shall be established, validated, maintained, implemented and recorded by the food product manufacturer to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment. Cleaning and/or sanitizing programmes shall specify at a minimum:

a. areas, items of equipment and utensils to be cleaned and/or sanitized;
b. responsibility for the tasks specified;
c. cleaning/sanitizing method and frequency;

d. monitoring and verification arrangements;
e. post-clean inspections;
f. pre start-up inspections.

3.1.9.3. Cleaning in place (CIP) systems

CIP systems shall be separated from active product lines. Parameters for CIP systems shall be defined and monitored (including type, concentration, contact time and temperature of any chemicals used).

3.1.9.4. Monitoring sanitation effectiveness

Cleaning and sanitation programmes shall be monitored at frequencies specified by the food product manufacturers to ensure their continuing suitability and effectiveness.

3.1.9.5. Cleaning Validation

Cleaning validation shall be performed in order to confirm the effectiveness of a cleaning procedure.

3.1.10. Pest control

Hygiene, cleaning, incoming materials inspection and monitoring procedures shall be implemented to avoid creating an environment conducive to pest activity.

3.1.10.1 Pest control programmes

The food manufacturers shall have a nominated person to manage pest control activities and/or deal with appointed expert contractors. Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, training requirements. The pest control programmes shall be based on integrated pest management (IPM) and chemicals as last resort. Programmes shall include a list of chemicals which are approved for use in specified areas of the establishment.

3.1.10.2. Preventing access

Premises shall be maintained in good repair. Holes, drains and other potential pest access points shall be sealed. External doors, windows or ventilation openings shall be designed to minimize the potential for entry of pests.

3.1.10.3 Harbourage and infestations

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

3.1.10.4. Monitoring and detection

Pest-monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.
Detectors and traps shall be of robust, tamper-resistant construction. They shall be appropriate for the target pest. The detectors and traps shall be inspected at a frequency intended to identify new pest activity. The results of inspections shall be analysed to identify trends.

3.1.10.5 Eradication

Eradication measures shall be put in place immediately after evidence of infestation is reported.
Pesticide use and application shall be restricted to trained operatives and shall be controlled to avoid product safety hazards.
Records of pesticide use shall be maintained to show the type, quantity and concentrations used; where, when and how applied, and the target pest.

3.1.11. Personnel hygiene and employees' facilities

Requirements for personal hygiene and behaviours proportional to the hazard posed to the process area or product shall be established and documented. All personnel, visitors and contractors shall be required to comply with the documented requirements.

3.1.11.1. Personnel hygiene facilities and toilets

Personnel hygiene facilities shall be available to ensure that the degree of personal hygiene required by the food manufacturer shall be maintained. The facilities shall be located close to the points where hygiene requirements apply and shall be clearly designated. Food manufacturer shall:

a. provide adequate numbers, locations and means of hygienically washing, drying and, where required, sanitizing hands (including wash-basins, supply of hot and cold or temperature controlled water, and soap and/or sanitizer);
b. have sinks designated for hand washing. The manufacturer is encouraged to use hands free water tap, separate from sinks for food use and equipment-cleaning stations;
c. provide an adequate number of flushing water toilets of appropriate hygienic design, each with hand-washing, drying and, where required, sanitizing facilities;
d. have employee hygiene facilities that do not open directly on to production, packing or storage areas;
e. have adequate changing facilities for personnel;
f. have changing facilities sited to enable personnel handling food to move to the production area in such a way that risk to the cleanliness of their Workwear is minimized.

3.1.11.2 Staff canteens and designated eating areas

Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross-contamination of production areas is minimized. Employees' own food shall be stored and consumed in designated areas only.

3.1.11.3. Work wear and protective clothing

Personnel who work in, or enter into, areas where exposed products and/or materials are handled shall wear appropriate work clothing, clean and in good condition (e.g. free from rips, tears or fraying material).
Clothing mandated for food protection or hygiene purposes shall not be used for any other purpose.
Workwear shall not have buttons and outside pockets above waist level. Zips or press stud fastenings are acceptable.
Workwear shall be laundered to standards and at intervals suitable for the intended use of the garments.
Workwear shall provide adequate coverage to ensure that hair, perspiration, etc. cannot contaminate the product.
Hair, beards, and moustaches shall be protected (i.e. completely enclosed) by restraints unless hazard analysis indicates otherwise.
Where gloves are used for product contact, they shall be clean and in good condition. Use of latex gloves should be avoided where possible.
Shoes for use in processing areas shall be fully enclosed and made from non-absorbent materials.
Personal protective equipment shall be designed to prevent product contamination and maintained in hygienic condition.

3.1.11.4. Health status

Employees shall undergo a medical examination prior to employment in food contact operations (including site catering). Medical examinations shall be carried out once in a year for communicable diseases. The medical examination shall include but not limited to the following:

a. Salmonella bacteria, Shigella, Salmonella typhi, vibrio cholera, intestinal viral infections and other intestinal parasites.
b. Typhoid fever, Viral hepatitis A, Viral hepatitis B.
c. Tubercle bacilli, chest X-ray tuberculosis infection
d. Communicable skin diseases.

3.1.11.5 Illness and injuries

Employees shall be required to report the following conditions to management for possible exclusion from food-handling areas: jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions (boils, cuts or sores) and discharges from the ear, eye or nose.
People known or suspected to be infected with, or carrying, a disease or illness transmissible through food shall be prevented from handling food or materials which come into contact with food.

3.1.11.6. First Aid Kit

First Aid Kits includes a range of products to deal with very common injuries such as small cuts, abrasions, and minor burns.

3.1.11.7 Personal cleanliness

Personnel in food production areas must maintain the highest degree of personal cleanliness. They shall be required to wash and, where required, sanitize hands:

a. before starting any food-handling activities;
b. immediately after using the toilet or blowing the nose;
c. immediately after handling any potentially contaminated material.

Personnel shall be required to refrain from sneezing or coughing over materials or products. Spitting (expectorating) shall be prohibited.
Fingernails shall be kept clean and trimmed.

3.1.11.8 Personal behaviour

A documented policy shall describe the behaviours required of personnel in processing, packing and storage areas.
When engaged in food handling activities personnel should refrain from behaviour which could result in contamination of food, for example:

a. smoking or vaping;
b. spitting;
c. chewing, eating, or drinking;
d. touching the mouth, nose or other places of possible contamination; and
e. sneezing or coughing over unprotected food.

Jewellery, watches, pins or other items such as false nails/eye lashes should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

3.1.11.9 Visitors and other persons from outside the food manufacturing premises

Visitors to food premises, including maintenance workers, in particular to food manufacturing, processing or handling areas, should, where appropriate, be instructed and supervised, wear protective clothing and adhere to the other personal hygiene provisions for personnel.
Visitors should be guided through a hygiene policy of the food manufacturer prior to visits and encouraged to report any type of illness/injury that may pose cross contamination issues.

3.1.12. Rework

Rework shall be stored, handled and used in such a way that product safety, quality, traceability and regulatory compliance is maintained.

3.1.12.1. Storage, identification and traceability

Stored rework shall be protected from exposure to microbiological, chemical or extraneous matter contamination.
Segregation requirements for rework (e.g. allergen) shall be documented and met.
Rework shall be clearly identified and/or labelled to allow traceability. Traceability records for rework shall be maintained.
The rework classification or the reason for rework designation shall be recorded (e.g. product name, production date, shift, line of origin, shelf-life).

Where rework activities involve removing a product from filled or wrapped packages, controls shall be put in place to ensure the removal and segregation of packaging materials and to avoid contamination of the product with extraneous matter.

3.1.13. Warehousing

Materials and products shall be stored in clean, dry, well-ventilated spaces protected from dust, condensation, fumes, odours or other sources of contamination.

3.1.13.1 Warehousing requirements

Effective control of warehousing temperature, humidity and other environmental conditions shall be provided where required by product or storage specifications.
It is recommended that where products are stacked, consideration is given to measures necessary to protect the lower layers.
All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.
Storage areas shall be designed or arranged to allow segregation of raw materials, work in progress and finished products, allergenic and non-allergenic food.
Waste materials and chemicals (cleaning products, lubricants, and pesticides) shall be stored separately.
A separate area or other means of segregating materials identified as non-conforming shall be provided.
Specified stock rotation systems, first in, first out (FIFO) and/or first expired, first out (FEFO) shall be applied.
Gasoline- or diesel-powered fork-lift trucks shall not be used in food ingredient or product storage areas.

3.1.13.2. Vehicles, conveyances, and containers

Vehicles, conveyances, and containers shall be maintained in a state of repair, cleanliness, and condition consistent with requirements given in relevant specifications.
Vehicles, conveyances, and containers shall provide protection against damage or contamination of the product. Control of temperature and humidity shall be applied and recorded by the food manufacturer.
Where the same vehicles, conveyances, and containers are used for food and non-food products, cleaning shall be carried out between loads.
Bulk containers shall be dedicated to food use only. Where required by the food manufacturer, bulk containers shall be dedicated to a specified material.

3.1.14. Transportation

Where applicable, conveyances and bulk containers should be designed and constructed so that they:

a. do not contaminate foods or packaging;
b. can be effectively cleaned and, where necessary, disinfected and dried;
c. permit effective separation of different foods or foods from non-food items that could cause contamination where necessary during transport;

d. provide effective protection from contamination, including dust and fumes;
e. can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsafe or unsuitable for consumption; and
f. allow any necessary temperature, humidity and other environmental conditions to be checked.

3.1.15. Product information and consumer awareness

a. Information shall be presented to consumers in such a way as to enable them to understand its importance and make informed choices. All manufactured food products shall be labelled with clear instructions or accompanied by adequate information to enable the next user in the food chain to handle, prepare, display, store, and/or use the product safely and correctly.
b. Information may also be provided by other means, such as company websites and advertisements, and may include storage, information that identifies food allergens in the product as ingredients, preparation and serving instructions applicable to the product.

3.1.16. Training and competency

All personnel engaged in food operations who come directly or indirectly into contact with food shall have sufficient understanding of food safety to ensure they have competence appropriate to the operations they are to perform. As results of the training, all personnel should be aware of their role and responsibility in protecting food from contamination or deterioration.
Induction and refresher training shall be provided and recorded.

The following evidences and documents shall be in place:

a. Training programme and plan
b. SOPs of training
c. Training records (e.g.: training material, attendance list, training evaluation, training certificates).

Elements to take into account in determining the extent of training required include but not limited to:

a. the nature of hazards associated with the food,
b. the manner in which the food is produced, processed, handled and packed, including the likelihood of contamination;
c. the extent and nature of processing or further preparation before consumption of the food;
d. the conditions under which the food will be stored;
e. the use and maintenance of instruments and equipment associated with food.
f. the principles of food hygiene applicable to the specific product manufactured;
g. the importance and practice of good personal hygiene, including proper hand washing and wearing, when needed, appropriate clothing, for food safety;
h. appropriate actions to take when food hygiene problems are observed.

3.1.17 Food defence bio vigilance and Bioterrorism

Each Manufacturer shall assess the hazard to products posed by potential acts of sabotage, vandalism or terrorism and shall put in place proportional protective measures. Potentially sensitive areas within

the establishment shall be identified, mapped, and subjected to access control. Where feasible, access should be physically restricted by use of locks, electronic card key or alternative systems.
Each Manufacturer shall have a documented, established and maintained procedure for a food fraud vulnerability assessment that:

a. Identifies potential vulnerabilities and threat.
b. Develops preventive measures.
c. Have the company put in place appropriate preventative measures to protect consumer health.
d. CCTV camera is encouraged

3.1.17. Work environment

Manufacturers shall determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity with the requirements of the food safety management system (FSMS). Those include but not limited to:

a. appropriate temperature and humidity within facility
b. Noise tolerance (maximum noise 90dBA for all workers in the factory for 8 hours)
c. Setting mechanism to control and retain harmful gaseous and smell which can harm the environment and the neighbouring areas.

3.2. Identification of Hazards and establishment of control measures

Manufacturers shall apply Hazard Analysis Critical Control Points (HACCP) from reception of raw materials up to final product with purpose of supplying the safe food to the consumers and providing other significant benefits, such as efficient processes that focus on critical areas resulting in fewer recalls through identification of problems before product is released.

The manufacturer shall develop, implement and maintain the HACCP manual including the following:

a. Assemble HACCP Team and Identify Scope
b. Describe product
c. Identify intended use and users
d. Construct flow diagram
e. On-site confirmation of flow diagram
f. List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards.
g. Determine the Critical Control Points (CCPs).
h. Establish validated critical limits.
i. Establish a system to monitor control of CCPs.
j. Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.
k. Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended (Validation of the HACCP Plan and validation of procedures).
l. Establish documentation concerning all procedures and records appropriate to these principles and their application.

Each food manufacturer shall have in place HACCP plan which include the assessment of risks associated with raw materials, processing steps and finished product and the verification activities.
The HACCP plan shall covers all steps related to raw materials, processing steps and finished product risk assessment.
HACCP Plan shall cover CCP, significant Hazard, Control Measures, Monitoring Requirements, Monitoring Frequency, Critical Limits, Corrections/Corrective Action, Responsibility, Records.

3.3 Personnel

The organization shall ensure that persons necessary to operate and maintain an effective GMP are competent.
Manufacturer shall ensure that the organizational structure is established, responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety system. Manufacturers shall have qualified and competent Key personnel composed of but not limited to:

a. in charge of production;
b. in charge of quality control /quality assurance.

The personnel in charge of production and the personnel in charge of quality control/quality assurance should have at least a bachelor's degree in Food sciences, Food Microbiology or Biotechnology. However, other qualifications, or other educational levels of study may be accepted after analysis and approval by the Authority.

Note: Manufacturer shall ensure that qualified competent personnel is fulltime employed and do not serve other related business.

3.4. Documentation

The manufacturers shall maintain comprehensive documentation system comprising but not limited to food safety prerequisites manual, quality manual (s), SOPs, work instructions, protocols, plans, specifications, records, reports, contracts.

3.4.1. Documentation categories

a. Manufacturers shall keep retained documents that cover what is called "records
b. Manufacturers shall keep maintained documents that will cover procedures, policies, etc. that would have been referred to as just "documents.

3.4.1.1. Maintained documents

The manufacturer shall maintain the following documents:

a. Food safety prerequisites manual(FSPM)
b. Quality manual/Laboratory manual
c. HACCP Manual
d. HACCP Plan
e. Product Characteristics
f. Description of validated Product Formulation

g. Corrective actions and preventive actions (CAPA)
h. Standard procedure for buildings
i. Standard procedure for premises & workspace
j. Standard procedure for utilities
k. Standard procedure for waste management
l. Standard procedure for equipment maintenance
m. Standard procedure for equipment calibration
n. Standard procedure for pest control
o. Standard procedure for Personnel hygiene & facilities
p. Standard procedure for Warehousing
q. Standard procedure for Cleaning and validation
r. Standard procedure for Prevention of cross contamination
s. Standard procedure for Rework handling
t. Standard procedure for Allergen Management
u. Standard procedure for personnel training
v. Standard procedure for Suppliers Approval
w. Standard procedure for material receiving, storage and handling
x. Standard procedure for handling and storage of finished product and dispatch
y. Standard procedure for Handling of by-product
z. Standard procedure for Labelling
aa. Standard procedure for Release of Product SOP/ Positive release
bb. Standard procedure for sampling Procedure
cc. Standard procedure for Traceability
dd. Sampling Plan
ee. Standard procedure for Stability Test
ff. Standard procedure for Batch Definition
gg. Standard procedure for Finished Product Quality Testing
hh. Standard procedure for Test Method and Method Validation
ii. Standard procedure for Control of non-conforming work
jj. Standard procedure for Customer complaint management
kk. Emergency preparedness and response plan SOP
ll. Visitor's and Change Procedure
mm. Preventive maintenance SOP
nn. Break down maintenance SOP
oo. Process flow diagram
pp. Process Narrative
qq. Zoning procedure
rr. Production general process
ss. Gowning procedure
tt. Batch record guiding document
uu. CIP Cleaning SOP

3.4.1.2. Retained documents

a. Waste disposal record
b. Water treatment record
c. Employee hygiene record

d. Allergen Monitoring record
e. GMP inspection record
f. CAPA Report
g. Non-conformance record
h. Annual audit plan
i. Internal audit program
j. Traceability report
k. Recall form
l. Recall report
m. Customer Complaint Record
n. Visitor's log book
o. Pest control map
p. The emergency response plan
q. Cleaning verification form/ record
r. Calibration plan
s. Equipment maintenance plan
t. Cleaning schedule
u. Lab waste disposal form
v. Incoming laboratory material and consumables inspection form
w. Sample collection form
x. Batch record
y. Certificate of analysis
z. Water quality test result
aa. Temperature/RH record form
bb. Finished product inspection form
cc. Incoming Raw Material inspection form
dd. Incoming goods inspection form
ee. Training attendance list
ff. Training matrix
gg. Supplier assessment form

3.4.2. Good documentation practice

a. Manufacturer shall design, prepare, review and distribute documents and the prepared documents shall comply with the relevant parts of the manufacturing and marketing authorizations
b. Manufacturer shall ensure that the documents:
    i. Are at least in one of the official languages accepted in Rwanda
    ii. Are approved, signed, and dated by appropriate authorized persons and a document shall not be changed without authorization;
    iii. have unambiguous contents and the title, nature, and purpose should be clearly stated and laid out in an orderly manner and easy to check.
    iv. be regularly reviewed and kept up to date.
c. Manufacturer may keep data and record electronically or may have data-processing systems or by photographic or other reliable means. In that case, the manufacturer shall ensure that concerned personnel have access to that information.

3.4.3. Good practices in quality control

A manufacturer shall not release finished food products for sale or supply, until their quality has been judged satisfactory. In order to comply with good practices in quality control, manufacturer

a. Shall have a testing laboratory with capacity to test critical parameters as described in the guide DIS/GDC/005 on critical parameters of processed food products.
b. Shall designate a person with appropriate qualifications in charge of the testing laboratory.
c. Shall have adequate resources including; equipment, reagents, personnel, furniture and other related materials to ensure that all the Quality Control arrangements are effectively and reliably carried out.
d. Shall ensure that testing cover raw materials, in-process/intermediate and final product.
e. Shall ensure that laboratory operations are carried out in accordance with written testing procedures with validated/ standardized methods.
f. shall ensure that laboratory testing equipment are calibrated by competent body.

Note: Each batch for high risk products should be tested for before realising it to the market

3.5. Complaints handling

Manufacturer shall ensure that all customer complaints received are registered, handled and responded to with the aim of resolving any issues in a timely and efficient manner.

3.6. Traceability system

The identification of materials in place shall be in a such that the end product batches are able to be traced back to the individual raw and packaging materials used, and to trace forward to the delivery of end products to customers.
When establishing and implementing the traceability system, the following shall be considered as a minimum:

a. relation of lots of received materials, ingredients and intermediate products to the end products;
b. reworking of materials/products;
c. distribution of the end product.

3. 7. Emergency preparedness and response

Manufacturer shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of manufacturing.

3.8. Self-inspection

Manufacturer shall conduct self-inspection/internal audit at planned intervals to:

a. Ensure compliance with good manufacturing practice in all aspects of production and quality control.
b. detects any shortcomings in the implementation of GMP and to recommend the necessary corrective actions.

There shall be an effective follow-up program and the company management shall evaluate both the self-inspection report and the corrective actions as necessary.
The self-inspection shall cover at least the following GMP areas:

i. Personnel
ii. Premises
iii. Equipment
iv. Utilities: Air, Water and Energy
v. Sanitation and hygiene
vi. Documentation
vii. Production and in process control
viii. Pest control
ix. Warehousing
x. Food defence

3.9. Change control

Changes may introduce new risks, modify existing risks or affect the effectiveness of control measures. Proper Management of Change shall assess all the risk of these changes, this requires taking adequate measures and ensures compliance with Safety and Product quality requirements.
The change control shall consider the following:

a. SOP describing the actions to be taken if a change is proposed to a raw material, product component, process equipment, process environment or site, method of production or testing or any other change that may affect product safety, quality or reproducibility of the process.
b. All changes that may affect product quality or reproducibility of the process shall be formally requested, documented and accepted.

4. GRANTING, REFUSAL AND VALIDITY OF CERTIFICATE OF COMPLIANCE WITH GMP

4.1. Granting certificate of compliance with GMP

Certificate of compliance with GMP is granted to food manufacturing facility complying with all good manufacturing practices requirements.

Manufacturer shall ensure that the GMP certificate is obtained before the release of product on market:

a. When additional lines are included
b. When two or more different premises on different sites are for one company.

4.2. Regulatory Action(s)

The Authority shall take the regulatory actions based on Minor, Major and Critical category of non-compliances.

a. **Critical non-compliance**: Is a failure of the management system that could results, or has resulted, in the highest risk of producing a product that is unsafe, fraudulent, which does not meet legal requirements or could damage brand reputation and poses an imminent serious risk to health. The food business is not able to rectify these issues during normal processes.

Examples include:

i. Inability to establish and implement HACCP plan
ii. Adulteration and fraud of food product;
iii. obstruction or hindrance of an inspector, including making any false or misleading statement;
iv. falsification of records or documents;
v. failure to take, or inability to take effective corrective actions by the dates established after having been given the opportunity to address the major non-compliance three (3) times.
vi. Multiple twelve major non-compliances identified from one GMP inspection will result into a critical non -compliance.

Authority have the ability to determine the other critical non-conformity.

b. **Major non-compliance:** The absence of, or a significant failure to implement and/or maintain conformance to the requirements of GMP (i.e. the absence of or failure to implement a complete GMP or part of the GMP without an agreed justification as to why).
Examples include:
   i. Fail to comply to critical food product safety parameters;
   ii. Absence and failure to establish and implement prerequisites programs (PRP)
   iii. Lack of traceability system (e.g.: lot /batch of product not properly identified in the food product premises)

c. Minor non-compliance: It represents either a management system weakness or minor issue that could lead to a major non-compliance if not addressed.
Example:
   i. very unclean premises
   ii. no hand washing facilities
   iii. monitoring frequency not respected in In-Line Verification system;
   iv. sampling plan not followed;
   v. verification records not complete;
   vi. minor sanitation issue;
   vii. calibration records missing;
   viii. training records not kept up to date.

4.3. Appeals

Any person aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within 15 working days from the date of notice.
The Authority shall within 30 working days from the date of appeal application review, vary or reject its own decision.
If a person is dissatisfied with a decision after review, he/she may appeal to the supervising Authority of Authority whose decision shall be final.

4.4. Administrative sanctions

Any person who contravenes the provisions of This regulation commits an administrative and upon conviction shall be liable to the penalties prescribed in Authority regulations related to regulatory service tariff/fee and fines in force.

4.5. Establishment of a scientific and advisory Committee

The Authority may establish a scientific and advisory committee comprising of internal and or external experts from different fields and scientific research to advise the Authority on Good Manufacturing Practices inspection matters.

4.6. Commencement

This regulation shall enter into force upon their approval and publication on the Authority's website.

4.7. Certificate and Validity

a. Upon fulfilling the requirements, the Authority shall issue a Certificate of good manufacturing practice.
b. The certificate shall be valid for a period of three (3) years.

5. REFERENCES

1. Guidelines for Good Manufacturing Practices of Food May,2019
2. Regulation for Good Manufacturing Practices of Food
3. General Principles of food hygiene CXC 1-1969 Adopted in 1969, Amended in 1999.Revises in 1997,2003, 2020.Editorial corrections in 2021.
4. ISO/TS 22002-1:2009(E), Prerequisite programmes on food safety
5. ISO 22000, 2018(E), Food safety management System-Requirements for any organization I the food chain.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Division manager of Food and Drugs Inspection and Compliance**	**Head of Department of Food and Drugs Inspection and Safety Monitoring**	**Quality Assurance Analyst**	**Director General**
Names	Dr. Marilyn M. MULINDAHABI	Dr. Eric NYIRIMIGABO	Mr. Theogene NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	25/01/2023	25/01/2023	25/01/2023	25/1/2023

APPENDICES

APPENDIX 1: GMP Inspection Application Requirements

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Inspection and Compliance Division
Document Type: **Checklist**		Doc. No : FDISM/FDIC/CKL/038
RWANDA FDA Rwanda Food and Drugs Authority	Title: **GOOD MANUFACTURING PRACTICES (GMP) INSPECTION APPLICATION REQUIREMENTS FOR FOOD PRODUCTS**	Revision Number : 1 Revision Date: : 30/10/2022 Effective Date : 30/12/2022 Review Due Date : 29/12/2025 Ref Doc. : FDISM/FDIC/GDL/004

No	Documents	Observation
1	Filled and signed application form	
2	Proof of payment of prescribed fees	
3	Food safety prerequisites manual(FSPM)	
4	License of premises for food product manufacturing	
5	List of all the products manufactured on site	
6	A copy of any warning letter or equivalent Regulatory action issued by any authority to which the site provides or has applied to provide the product.	
7	Corrective action (CA) related to the GMP inspection report observations/non-compliances if any.	
8	GMP inspection report issued by other competent authorities, if any.	
9	Current GMP Certificate/ISO 22000/HACCP/FSSC 22000/BRC if any.	
10	Product description including brief description of product validated formulation, product testing results and stability study report.	
11	Self-inspection report.	
12	Quality Manual/Laboratory Manual or equivalent.	
13	The most recent batch records.	
14	A list of any recalls or any Market complaints register in the last three years.	
15	Contract or agreement between manufacturer and the outsourced testing laboratory (List of Subcontractor).	

APPENDIX 2: Application form for Good Manufacturing Practice inspection for food product manufacturing facilities

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Inspection and Compliance Division
Document Type: **Form**		Doc. No : FDISM/FDIC/FOM/007
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Application form for Good Manufacturing Practice inspection for food product manufacturing facilities**	Revision Number : 0 Revision Date: : 30/10/2022 Effective Date : 30/12/2022 Review Due Date : 29/12/2025 Ref Doc. : FDISM/FDIC/GDL/004

Applicant to fill the following sections

1. **Particulars of the Applicant**

Name_____

Physical Address_____

Country_____Telephone_____

E-mail_____

2. **Particulars of Manufacturing Site to be Inspected**

Name of site_____

Physical Address (if different from 1. above)

_____

Country_____Tel_____

E-mail: _____

***Note**: Separate application to be filled in for each individual site*

3. **Contact Person on Site**

Name of contact person_____

Tel: _____Fax: _____

E-mail: _____

4. **Authorized Representative/Agent in Rwanda**

Name of Local Technical Representative_____

Tel: _____ E-mail: _____

5. **Type of Food product risk categories**

Type of food product (*double click to check applicable box)*

a. High risk foods for special nutritional purposes ☐
b. High risk foods for general purpose ☐
c. Low risk foods ☐

6. **List of the products to be registered**

Brand Name	Common Name	Form of the physical characteristic of	Packaging unit(s) in weigh or	Packaging container(e.g:Bottle,Box , sachet etc)

		the food (e.g: Solid, liquid etc)	volume or number	

7. Registration of Products in Rwanda

Have you registered any products in Rwanda YES ☐ NO ☐

Have you submitted product dossier for registration from the production line(s) applied for inspection? YES ☐ NO ☐ (If "YES", list of the products in the table below)

Brand Name	Common Name	Form of the physical characteristic of the food (e.g: Solid, liquid etc)	Packaging unit(s) in weigh or volume or number	Packaging container(e.g:Bottle,Box , sachet etc)

8. Inspection Applied for (Double click to check applicable box)

☐ First Inspection
☐ Routine Inspection (state previous inspection dates ……*DD/MM/YYYY*)
☐ Re-inspection (after failure)
☐ Other *(please specify)* …….

9. Major Site Changes Since Last Inspection

Provide summary of changes to personnel, equipment, buildings, specifications, computer systems, products (type, range or category), suppliers and contractors since last inspection, below or as an Attachment to this form.

……
……
……
……

Production Lines to be Inspected *(Please tick or fill in the applicable boxes)*

		Yes	No	Building Block name/Number	Number of production lines
1	**MANUFACTURING OPERATIONS**				
1.1.	**High risk Foods for special nutritional purposes**				
	A. Infant formulae and follow-up formulae				

	B. Complementary food for infants and young children				
	C. Foods intended for special medical purposes				
	D. Formula foods for use in weight control diets				
	E. Food supplements				
	e.i. Vitamins and Minerals				
	e. ii. Amino acids				
	e.iii. Essential Fatty acids				
	e. iv. Plant, plant extracts and other herbal based supplement				
	e.v.Enzymes and other metabolites				
	e.vi.Prebiotics				
	e.vii.Probiotics				
	e.viii.Animal products and animal extracts				
	e.ix.Protein Concentrates				
	Other and specify				
1.2.	**High risk Food for general purpose**				
	A. Milk and milk products				
	a.i.Processed liquid milk				
	a.ii.Flavoured dairy-based drinks				
	a.iii.Fermented and renneted milk products				
	a.iv .Condensed milk and evaporated milk				
	a.v.Cream and cream analogue				
	a.vi. Milk powder and cream powder				
	a.vii.Cheese and analogues				
	a.viii.Dairy-based desserts				
	a.ix.Butter				
	a.x. Ghee				
	B.Meat and meat products				
	b.i.Processed meat, poultry and game products				
	b.ii.Processed comminuted meat, poultry and game products				
	b.iii.Edible casing				
	C. Fish and Fish products including molluscs, crustaceans and echinoderms				
	c.i.Processed fish and fish products including molluscs, crustaceans and echinoderms				
	c.ii.Semi-preserved fish and fish products including molluscs, crustaceans and echinoderms				
	c.iii.Fully preserved, canned or fermented fish and fish products including molluscs, crustaceans and echinoderms				
	D. Eggs and egg products				
	d.i. Eggs products				
	d.ii. Preserved eggs				

	d.iii.Egg-based desserts				
	E. Spices ,soup, sauces, salads and proteins products				
	e.i.Herbs,spices,seasonings and condiments				
	e. ii. Mustards				
	e.iii. Soups and broths				
	e. iv. Sauces and like products				
	e.v.Salads				
	e.vi.Yeast and similar products				
	e.viii.Soybean products				
	e. viii. Other protein products				
	F. Processed vegetables and vegetable products				
	f.i.Dried vegetables				
	f.ii.Vegetables in vinegar,oil,brine or soy sauce				
	f.iii. Fermented vegetable products				
	f.vi. Cooked,blached or fried vegetables				
	G. Ready to eat savouries				
	g.i. Processed nuts and nuts products				
	g.ii.Desicated nuts				
	H. Composite foods				
	I. Potable Water(mineral/drinking water)				
	J. Herbal tea				
	Other and specify				
1.3.	**Low risk food**				
	A .Fats and oil, and fat emulsions				
	a.i.Vegetable oil and fat				
	a.ii.Fat emulsions containing less than 80%				
	a.iii.Fat emulsion containing more than 80%				
	a.iv Animal fat				
	a.v.Fat-based desserts				
	B. Edible ices, including sherbet and sorbet				
	C.Flours				
	c.i.Maize Flour				
	c.ii.Wheat Flour				
	c.iii Sorghum Flour				
	c.iv.Rice Flour				
	c.v mixed Flour				
	c.vi Other type of flour and specify				
	D.Processed Fruits and fruits products				
	d.i. Dried fruit				
	d.ii. Fruits in vinegar, oil or brine canned or bottled fruit				
	d.iii.Jams,jellies,marmalades,fruits-based spreads				
	d.iv. Fruit preparations				

	d.v.Fruits-based desserts				
	d.vi. Fermented fruit products				
	d.vii. Cooked or fried fruit				
	d.viii.Fruits juices and nectars and their concentrates				
	E. Confectionaries				
	e.i. Hard and soft candy				
	e. ii. Chewing gums				
	F. Coffee,Tea,Coccoa and their products				
	f.i.Coffee				
	f.ii.Coffee products				
	f.iii. Tea				
	f.iv.Coccoa				
	f.v.Coccoa products				
	G. Cereals and cereal products				
	g.i Whole, broken or flaked grains				
	g.ii.Cereal starches				
	g.iii.Breakfast cereals including rolled oats				
	g. iv. Pastas and noodles and like products				
	g.v.Cereal and starch based desserts				
	g.vi Pre-cooked or processed rice products				
	H. Bakery wares				
	h.i.Breads,cake,biscuits,chappatti,crackers,cookies				
	h.ii.Fine bakery wares and mixes				
	I. Sweeteners including Honey				
	i.i. Sugar				
	i.ii. Other sugars and syrups				
	i.iii. Honey				
	i.iv.Table-top sweeteners				
	J.Non Alcoholic Beverages				
	j.i.Soft drinks				
	j.ii.Cereal based drinks				
	j.iii.Ice rallies				
	j.iv.Powdered drinks				
	K. Alcoholic beverages				
	k.i. Portable Spirts and liquors				
	k. ii. Wines and Rosella alcoholic drink				
	k.iii. Cider and Perry, Mead alcoholic drinks				
	k.iv.Cereal based alcoholic beverages				
	k.v.Non cereal based alcoholic beverages, Specify				
	L.Salt and salt substitutes				
	M. Vinegars				
	Other and specify				

2	**PACKAGING OPERATIONS**				
	2.i. specify the product				

10. Declaration

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s). I also commit to welcome the Rwanda FDA GMP inspectors for the inspection.

Signature of applicant……. Date……

Name…….. Designation.....

***Notes**:*

1.Please submit a copy of the current Site Master File together with this application (refer to Guideline on preparation of a Site Master File)

2. Submit the completed application together with proof of payment of the appropriate fees, to the Director General Rwanda Food and Drugs Authority.

This box is to be completed by Rwanda FDA official only

Inspection Reference Number:		
Assigned to:	*Lead GMP Inspector*	*Team GMP Inspector(s)*
Name		
Assigned by: *Name*	*Title:* *Date:*	*signature:*

APPENDIX 3: Food Safety Prerequisite Manual (FSPM) Content

Rwanda Food and Drugs Authority
Nyarutarama Plaza, KG 9 Avenue
P.O. Box: 1948 Kigali - Rwanda
Email: info@rwandafda.gov.rw
website: www.rwandafda.gov.rw

QMS Nº: FDISM/FDIC/FMT/006
Revision No: 0
Effective Date: 30/12/2022

FOOD SAFETY PREREQUISITE MANUAL (FSPM) CONTENT

1. General information on the manufacturer

1.1 Contact information on the manufacturer

a. name and official address of the manufacturer;
b. names and street addresses of the site, buildings and production units located on the site;
c. contact information of the manufacturer including 24-hour telephone number of the contact personnel in the case of product defects or recalls;
d. identification number of the site as e.g. global positioning system (GPS)

1.2 Authorized food manufacturing activities of the site

a. copy of the valid manufacturing authorization issued by the relevant competent authority.
b. brief description of manufacture, import, export, distribution and other activities as authorized by the relevant competent authorities
c. type of products currently manufactured on-site
d. list of GMP inspections of the site within the last five years; including dates and name/country of the competent authority having performed the inspection.
e. A copy of the current GMP certificate

1.3 Any other manufacturing activities carried out on the site

a. description of other activities performed on site, if any.

2. Quality management/Food safety management system

2.1 The quality management system of the manufacturer

a. Brief description of the quality management system/food safety management systems run by the company and reference to the standards used;
b. Responsibilities related to the maintaining of the quality management system/food safety management system including senior management;

2.2 Manufacturing process

Detailed description of qualification requirements (education and work experience) of the authorized person(s)/qualified person(s).

2.3 Management of suppliers and contractors

a. Method of selection and approving the suppliers

b. Certification and validation use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis;
c. List of contract for outsourced services such as laboratory testing, pest control, waste disposal, etc.
d. Addresses and contact information for manufacturers or distributor e.g. packaging material, raw materials, cleaning materials, etc.

2.4 Food safety risk management

brief description of identification, prevention and control of potential hazards.

2.5 Product description

a. Brief description of product validated formulation.
b. Product testing results.
c. Stability study report.

3. Personnel

a. Organigram showing the arrangements for quality management, production and quality control positions/titles, including senior management and authorized person(s)/qualified person(s); and
b. Number of employees, job descriptions, qualifications, training obtained for employees engaged in the quality management, production, quality control, storage and distribution, respectively.

4. Premises and equipment

4.1 Premises

a. short description of plant: size of the site and list of buildings.
b. Layouts and flowcharts of the production areas

4.1.1 Brief description of ventilation in the facility

4.1.2 Brief description of water systems

4.1.3 Brief description of other relevant utilities such as steam, compressed air, nitrogen, etc. Where applicable

4.2 Equipment

4.2.1 Listing of major production and control laboratory equipment.

4.2.2 Cleaning and sanitation

a. brief description of cleaning and sanitation methods of product contact surfaces (i.e. manual cleaning, automatic cleaning, etc.).

5. Documentation

a. description of documentation system (i.e. electronic, manual); and
b. when documents and records are stored or archived off-site: list of types of documents/ records; name and address of storage site; and an estimate of time required to retrieve documents from the off-site archive.

6. Production

6.1 Type of products

a. type of products manufactured including:
b. toxic or hazardous substances handled

6.2 Process validation

a. brief description of general policy for process validation; and
b. policy for reprocessing or reworking.

6.3 Material management and warehousing

a. arrangements for the handling of raw materials, packaging materials, bulk and finished products including sampling, quarantine, release and storage; and
b. arrangements for the handling of rejected materials and products.

7. Quality control

description of the QC activities carried out on the site in terms of physical, chemical and microbiological and biological testing.

8. Distribution, complaints, product defects and recalls

8.1 Distribution (to the part under the responsibility of the manufacturer)

a. brief description of the system to ensure appropriate environmental conditions during distribution;
b. arrangements for product distribution and methods by which product traceability is maintained; and

8.2 Complaints, product defects and recalls

a. brief description of the system for handling complaints, product defects and recalls.

9. Self-inspections

a. short description of the self-inspection system with focus on criteria used for selection of the areas to be covered during planned inspections, practical arrangements and follow-up activities.
b. Annexes to a submission of a FSMP

SOPs:

Annex 1 Copy of valid manufacturing authorization
Annex 2 List of food product manufactured including their common name
Annex 3 Copy of valid GMP certificate
Annex 4 List of contract manufacturers and laboratories including the addresses and contact information, and flowcharts of the supply chains for these outsourced activities
Annex 5 Organizational charts
Annex 6 Layouts of production areas including material and personnel flows, general flowcharts of manufacturing processes of each product type
Annex 7 Schematic drawings of water systems
Annex 8 List of major production and laboratory equipment

APPENDIX 4: Content of Quality Manual

Rwanda Food and Drugs Authority
Nyarutarama Plaza, KG 9 Avenue
P.O. Box: 1948 Kigali - Rwanda
Email: info@rwandafda.gov.rw
website: www.rwandafda.gov.rw

QMS Nº: FDISM/FDIC/FMT/007
Revision No: 0
Effective Date: 30/12/2022

CONTENT OF QUALITY MANUAL

Introduction

The quality manual should begin with an introduction that contains a brief overview of the quality manual and laboratory. Examples of information to include in the introduction are:

- a description of the laboratory including its history and its activities.
- a description of the processes for how updates will be managed, and why they need to occur.

Organization and management

The description of the laboratory organization should include:

- an organizational chart depicting the hierarchy of responsibility and authority;

Quality policy

A section describing the quality policies should be one of the first topics to address in the quality manual because it forms the basis for the quality system: the mission, objectives, and roles, from which all the activities of the laboratory will be focused.

In this section, the management commitment to quality should be stated. All future actions of the laboratory will be directed by the quality policies.

A quality policy should be written for each of the 12 quality elements.

Personnel

The quality manual should address personnel policies. Some of the important information that needs to be referenced includes:

- **job descriptions**
- a **personnel list**
- **an organizational chart and conditions of recruitment**

Document control

The policies and processes needed for document control should be described in the quality manual. Careful document control is very important in the laboratory, and is needed to:

- assure up-to-date and accurate descriptions and procedures;
- assure proper archiving;
- produce accurate and reliable reports;
- follow trends in the laboratory;
- maintain confidentiality of patient records and information.

Accommodation and environment

This section should include information about the facilities and environmental requirements for the laboratory. The quality manual might include:

- a map of the laboratory premises, showing all space that the laboratory uses, and restricted points of access.
- requirements for laboratory signage. For example, signs might be needed for the specimen collection or sampling room. Safety instructions and emergency exits will require signs or charts of instructions. Use of biological hazard signs should be defined.
- environmental requirements for the laboratory. These requirements will need to be defined, including provision for verifying that the requirements are met. The definitions of environmental needs, or standards, should reflect how much variation can be tolerated.

Instruments, reagents, and consumables management

Requirements for instrument/equipment management should be addressed, including:

- instrument logbooks;
- written procedures for use;
- quality control procedures;
- maintenance procedures;
- procedures for instrument replacement and disposal.

Safety

Defining practices, processes, and procedures to maintain a safe environment in the laboratory is very important. Safety considerations are of concern to staff, to all who might come in contact with the laboratory, and with the community. All staff should be aware of the manual and should proceed according to its contents.

Examination procedures

Examination procedures are detailed in an SOP. For the description of the use and management of equipment, instructions should be used instead of standard operating procedures.

Quality control

The quality control procedures are normally included in each specific testing procedure, or SOP. However, the quality manual should have a statement regarding the commitment of the laboratory; there should be a reference to the link with other control procedures. Legal or ethical considerations should be mentioned.

Corrective/ preventive actions, internal audits

An essential part of the quality system is continuous improvement, and this is accomplished in part by reviewing and understanding all problems and errors. The processes for this to be referenced in the quality manual.

Both internal and external audits provide a means for continuous improvement of the system. Internal audits are required under the ISO 15189 scheme, and how they will be conducted must be described in the quality manual

APPENDIX 5: GMP Inspection Checklist

Format: QMS/FMT/002 Revision No: 1 Effective Date: 20 June 2022	Department/Division/Office/Unit	Food and Drugs Inspection and Compliance Division	
Document Type: **Checklist**		Doc. No	: FDISM/FDIC/CKL/058
RWANDA FDA Rwanda Food and Drugs Authority	Title: **GOOD MANUFACTURING PRACTICES (GMP) INSPECTION CHECKLIST**	Revision Number	: 0
		Revision Date:	: 30/10/2022
		Effective Date	: 30/12/2022
		Review Due Date	: 29/12/2025
		Ref Doc.	: FDISM/FDIC/GDL/004

Letter of authority to inspect: Ref. No….....
Date……
Name of production supervisor.....
Qualification of production supervisor:……
Name of food facility:……
Name of food processed/packed:……
Name of owner:…….....
Name of Director/Manager:……
Address:……
Tel. No:……
Email address:……
Premises License/permit No:……
Any other certificate of conformity No:……of (date)……
Purpose of inspection :…….

No.	**PREMISES AND EQUIPMENTS**				
1	**Location of Premises**	**Yes**	**No**	**N/A**	**REMARKS**
1.1	Located in industrial area **(m)**				
1.2	Environmentally polluted areas **(M)**				
1.3	Areas where wastes, either solid or liquid, cannot be removed effectively **(M)**				
2	**Design and layout of food manufacturing premises**				
2.1	Buildings are of durable construction which presents no hazard to the product.**(M)**				
2.2	The design and layout permit adequate cleaning.**(m)**				
2.3	Premises is properly maintained to minimize or prevent cross contamination **.(M)**				
2.4	One-directional production flow.**(m)**				
2.5	The building is adequately fenced to keep out larger animals such as dogs or cats**(m)**				

3	**Internal structures and fittings**				
3.1	Space used for food manufacturing is adequate(personnel in working area not crowded, demarcated areas for processing to prevent cross contamination) **(m)**				
3.2	Windows and vents are screened with pest-proof nets**(m)**				
3.3	walls and partitions shall have a smooth surface up to a height appropriate to the operation; **(m)**				
3.4	floors shall be made by smooth material free from cracks and joints to allow adequate drainage and cleaning; **(m)**				
3.5	ceilings and overhead fixtures (e.g. lighting) shall be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles; **(m)**				
3.6	doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect**(m)**				
3.7	Work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. **(m)**				
3.8	Sufficient space for placement of equipment and materials provided (minimum space between equipment and walls is 60 cm) **(m)**				
4	**Utilities : Air**				
4.1	Ventilation systems designed and constructed such that air does not flow from contaminated or raw areas to clean areas **(m)**				
4.2	Ventilation system shall ensure control of unwanted odours which might affect the suitability of food **(m)**				
4.3	Specified air pressure differentials is maintained. **(m)**				
	Ventilation systems are accessible for cleaning, filter changing and maintenance **(m)**				
4.4	Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling are constructed and maintained so as to prevent contamination **(M)**				
4.5	Where oil is used for compressors and there is potential for the air to come into contact with the product, the oil used shall be food grade.				

	Alternatively, use of oil free compressors is recommended **(m)**				
5	**Water**				
5.1.	Water quality (according to purpose of its use) complying with specifications for Portable, Purified Water or distilled water **(M)**				
5.2.	Water treatment system is effective and consists of carbon and sand filters, de-mineralisers, UV light/ozone systems-(*where applicable*) **(M)**				
5.3	Sufficient supply of potable water or distilled water to meet the needs of the production process(es)- (where applicable) **(M)**				
5.4	Appropriate storage for potable water and distribution system. **(M)**				
5.5	Chlorination, Ozonation or any other chemical treatment for disinfection, the residual level thereof at the point of use remains within limits given in relevant specifications. **(M)**				
5.6	Water used as a product ingredient (including ice or steam) or in contact with products or product surfaces, meets specified quality and microbiological requirements relevant to the product. **(C)**				
5.7	Water for cleaning or applications where there is a risk of indirect product contact (e.g. jacketed vessels, heat exchangers) shall meet specified quality and microbiological requirements relevant to the application **(m)**				
5.8	Non-potable water shall have a separate supply system that is labelled and not connected to the potable water system **(M)**				
5.9	Water that comes into contact with the product shall flow through food grade pipes and the later shall be disinfected **(M)**				
5.10	Water recirculated for reuse and water recovered from e.g. food processing operations, by evaporation and/or filtration is treated where necessary to ensure that the water does not compromise the safety and suitability of food. **(m)**				
6	**Energy and Lighting**				
6.1	Adequate natural or artificial lighting is provided to enable the food business to operate in a hygienic manner. The intensity should be adequate to the nature of the operation.**(m)**				

6.2	Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements**(m)**				
6.3	All other source of combustible materials in food processing and production shall not be a source of food contamination. (m)				
7	**Waste disposal**				
7.1	Procedure for waste disposal is in place to ensure that waste materials are identified, collected, removed and disposed of.**(M)**				
7.2	Containers for waste and inedible or hazardous substances are clearly identified and labelled for their intended purpose and located in a designated area. **(M)**				
7.3	Dedicated, labelled and locked area for temporarily storing of waste before final disposal is available. **(m)**				
7.4	Drains are designed, constructed and located so that the risk of contamination of materials or products is avoided. **(M)**				
7.5	Drains have sufficient capacity to remove expected flow loads.**(M)**				
8	**Equipment suitability, cleaning and maintenance**				
8.1	Product contact surfaces are made from food grade materials (they are impermeable, rust or corrosion free, non-toxic and inert materials). **(C)**				
8.2	Equipment used for thermal processes shall allow to monitor and display temperature change and holding conditions given in relevant product specifications.**(M)**				
8.3	Mixing tanks are labelled and indicate graduated levels.**(M)**				
8.4	Equipment for the monitoring and control of key safety and quality parameters (e.g. temperature and pressure) are calibrated **(M)**				
9	**Preventive and corrective maintenance**				
9.1	A preventive maintenance programme (SOP and records) is in place and include all devices used to monitor and/or control food safety hazards.**(M)**				
9.2	Corrective maintenance shall be carried out in such a way to minimize risk of contamination. **(m)**				
9.3	Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or indirect contact with the product.**(m)**				

9.4	The procedure for releasing maintained equipment back to production includes clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection.**(m)**				
9.5	Maintenance personnel are trained in the product hazards associated with their activities. **(m)**				
10	**Management of purchased materials**				
10.1.	There shall be a defined process for the selection, approval and monitoring of suppliers. **(M)**				
10.2.	Monitoring the performance of suppliers to assure continued approval status. **(m)**				
11	**Incoming material requirements (raw/ingredients/packaging)**				
11.1.	Delivery vehicles are checked prior to, and during, offloading to verify that the quality and safety of the material was maintained during transit. **(m)**				
11.2.	Materials are inspected, tested or supported by certificate of analysis to verify conformity with specified requirements prior to acceptance or use **(M)**				
11.3.	Materials which do not conform to relevant specifications shall be handled under a documented procedure which ensures they are prevented from unintended use. **(m)**				
12	**Measure for prevention of cross-contamination**				
12.1	Procedure in place and implemented to prevent, control or detect potential physical, chemical and microbiological contamination **(M)**				
13	**Food allergens management**				
13.1	Procedure in place and implemented to prevent, control or detect unintended allergen cross-contact. **(m)**				
14	**Cleaning and sanitizing**				
14.1	Cleaning and sanitizing programmes are established, validated, maintained, implemented and recorded. **(M)**				
14.2	Cleaning and sanitizing agents are clearly identified, food grade, stored separately from any related food material.**(m)**				
14.3	CIP systems are separated from active product lines.**(m)**				
15	**Pest Control**				

15.1	Pest management programmes based on integrated pest management (IPM) are established, implemented and documented. **(m)**				
15.2	Material found to be infested are handled in such a way as to prevent contamination of other materials.**(m)**				
16	**Personnel hygiene and employees' facilities**				
16.1	Facility equipped with adequate and convenient hand free washing facilities (such as electrical water tap with sensor, foot pedal and nerf pedal).**(m)**				
16.2	changing facilities are adequate and integrate within the facility to avoid cross-contamination and furniture in place. **(m)**				
16.3	Appropriate toilet facilities located far from production area for ach gender equipped with water flushing mechanism, cover, closing doors and hand washing facility. Toilets shall be isolated from production area but not far from manufacturing facility **(M)**				
16.4	The facility shall allocate the staff eating area separate from production area.**(m)**				
16.5	Appropriate personnel protective wear and gear shall be available within a facility and shall not be used out of the facility .**(m)**				
16.6	Medical examinations certificates (Tuberculosis, Hepatitis A, intestinal worms, communicable skin diseases) for employees are available. **(m)**				
16.7	Availability of first aid Kit **(m)**				
16.8	Employees known or suspected to be infected with communicable diseases are prevented from handling food or materials which come into contact with food. **(m)**				
16.9	Jewellery, watches, pins or other prohibited items are not allowed in food handling areas.**(m)**				
16.10	Instructions in place restricting the visitors from accessing the food manufacturing areas. **(m)**				
17	**Rework**				
17.1	Rework shall be stored, handled and used in such a way that product safety, quality, traceability is maintained. **(m)**				
17.2	**Warehousing**				

17.2.1	Warehouse of raw material and finished products shall be accessible for load and offloading and separated. **(M)**				
17.2.2	Warehouse shall be enough to accommodate intended material. Warehouse shall be clean, dry, well-ventilated spaces protected from dust and temperature/ humidity controlled. If not otherwise specify **(M)**				
17.2.3	All materials and products shall be stored off the floor and with sufficient space between the material and the walls at least 60 cm. **(m)**				
17.2.4	Non-conforming or unsafe product and chemicals (cleaning products, lubricants, and pesticides) shall be stored separately.**(m)**				
17.2.5	Rotation systems, first in, first out (FIFO) and/or first expired, first out (FEFO) shall be applied .(m)				
18	**Product information and consumer awareness**				
	All manufactured food products shall have a validated formulation and be labelled as per product standard specification.**(C)**				
19	**Training and competency**				
	Training programme and plan, SOPs of training, Training records and job description shall be in place and effectively implemented.**(M)**				
20	**Food defence bio vigilance and Bioterrorism**				
20.1	Each Manufacturer shall have food defence program (Processing line security, storage security, food defence procedures against hazardous materials such as pesticides). **(m)**				
20.2	Each Manufacturer shall have a documented, established and maintained procedure for a food fraud vulnerability assessment that: a) Identifies potential vulnerabilities and threat. b) Develops preventive measures. c)Have the company put in place appropriate preventative measures to protect consumer health. d) CCTV camera is encouraged. **(m)**				
21	**Work environment**				
	Conducive working environment shall be maintained (appropriate temperature and humidity within facility, Noise level shall be tolerant, harmful gaseous and smell shall be controlled). **(m)**				
22	**HACCP**				

	Is a hazard analysis conducted for each process step in the manufacturing of the food item? Was the hazard analysis conducted by a competent team? **(M)**				
	Is the hazard analysis indicating significant hazards and Critical Control Points (CCPs)? **(M)**				
	Are Critical Limits established for each CCP? **(M)**				
	Are monitoring procedures established for each CCP? Are CCPs effectively implemented? **(M)**				
	Are corrective actions established for each CCP in the event critical limits are exceeded? **(M)**				
	Are all HACCP-related record-keeping and documentation procedures established and effectively implemented? **(M)**				
	In overall, Are HACCP manual and plan in place and implemented? **(C)**				
23	**Personnel**				
	The organization shall ensure that persons (In charge of Production/quality control/ quality insurance) necessary to operate and maintain an effective GMP are competent on basis of appropriate education , training, and/or experience (C)				
24	**Documentation**				
	Are all relevant documentations necessary for a successful GMP available, distributed maintained (reviewed and updated), and retained (e.g.: prerequisites manual, quality manual (s), SOPs, work instructions, protocols, plans, specifications, records, reports, contracts). **(M)**				
25	**Good practices in quality control**				
	Manufacturer shall have a testing laboratory with capacity to test critical parameters as described in a pertaining standard. **(M)**				
	Manufacturer shall ensure that laboratory operations are done based on a SOP **(m)**				

	Manufacturer shall avail sampling plan, sampling procedure and positive release procedure **(m)**				
26	**Customer Complaint handling**				
	Manufacturer shall avail customer complaint record and how received complaints were handled (CAPA) **(m)**				
27	**Traceability system**				
	The identification of materials in place shall be in a such that the end product batches are able to be traced back to the individual raw and packaging materials used, and to trace forward to the delivery of end products to customers **(m)**				
28	**Emergency preparedness and response**				
	Manufacturer shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety.**(m)**				
29	**Self-inspection**				
	Manufacturer shall conduct self-inspection/internal audit at planned intervals**(m)**				
30	**Change control**				
	Manufacturer shall establish a SOP describing the actions to be taken if a change is made (e.g: to a raw material, product component, process equipment, process environment or site, method of production or testing or any other change that may affect product safety, quality or reproducibility of the process). **(m)**				

Key: **(m): means minor non- compliances**

(M):means major non- compliances

(C):means critical non- compliances

APPENDIX 6: Certificate of Compliance with GMP of Food Products

Rwanda Food and Drugs Authority
Nyarutarama Plaza, KG 9 Avenue
P.O. Box: 1948 Kigali - Rwanda
Email: info@rwandafda.gov.rw
website: www.rwandafda.gov.rw

QMS Nº: FDISM/FDIC/FMT/013
Revision No: 1
Effective Date: 30/12/2022

CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE OF FOOD PRODUCTS

Certificate Nº: Issue Date: *DD/MM/YYYY* Valid up to: *DD/MM/YYYY*

This is to certify that the Food manufacturing facility with following details:

Name of facility:
Physical address:
License number:
Country:
E-mail: **Telephone:**

Has been **inspected/Assessed** by the Rwanda Food and Drugs Authority for compliance with the Good Manufacturing Practice Guidelines.

Based on the **Physical Inspection/Virtual Inspection/Desk Assessment/Reliance Pathway** carried out on DD/MM/YYY, DD/MM/YYY, and DD/MM/YYY it is certified that the Food manufacturing facility indicated on this certificate complies with Good Manufacturing Practice for products listed in Table below:

Nº	Product category	Product type	Manufacturing activities
1			
2			

The responsibility for the quality of the individual batches of the food products manufactured through this process lies with the manufacturer.
This certificate becomes invalid if the activities or the categories certified change or if the facility is no longer rated to be in compliance with Good Manufacturing Practice.

The following should be written on the certificate: Based on HACCP and ISO 22000

Names, Signature and Stamp of the institution
Director General

END OF DOCUMENT