Available online on 15.09.2025 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Full Text Article

Research Article

Formulation of Functional Food Supplements: Case Study of Manufacturing Process Optimization at '*Sarepta Production*', Burkina Faso

Mimtiri S. ZONGO,[1] Luc ZONGO,[1,2,3]* Modeste W. OUEDRAOGO,[1] Salfo OUEDRAOGO,[4] Rosemary R. CANFUA,[5] Heiko LANGE,[6,7] Lucien KABORE,[1] Wilfried F.P. TRAORE,[1] Yilédoma T. M. LENGANE,[1] Davy P-W BEMBAMBA,[1] Aline F. TIENDREBEOGO, [8] Elie KABRE. [9,10]

1. Hôpital Saint Camillus de Ouagadougou (HOSCO), 09 BP 444 Ouagadougou 09, Ouagadougou, Burkina Faso.
2. Faculté des Sciences de Santé, Université Saint Thomas d'Aquin (USTA), 06 BP 10212 Ouagadougou 06, Burkina Faso.
3. Centre de Recherche Biomoléculaire Pietro Annigoni (CERBA) 01 BP 216 Ouagadougou 01. Burkina Faso.
4. Département de Médecine et Pharmacopée Traditionnelles-Pharmacie (Mephatra-PH), Institut de Recherche en Science de la Santé (IRSS/CNRST), 03 BP 7047 Ouaga 03, Burkina Faso.
5. Global Access to Affordable Essential Medicines and Safe Alternative Therapies, P.O. Box 458, Kampala, Uganda.
6. University of Milano-Bicocca, Department of Earth and Environmental Sciences, Piazza della Scienza 1, 20126 Milan, Italy.
7. NBFC – National Biodiversity Future Center, Piazza Marina, 61 90133 Palermo, Italy
8. Pharmacie Saint François d'Assise, 06 BP 9888 Ouagadougou 06
9. gence Nationale pour la Sécurité Sanitaire de l'Environnement, de l'Alimentation, du Travail et des produits de santé (ANSSEAT), 09 BP 24 Ouagadougou, Burkina Faso
10. Université Joseph KI-ZERBO (UJKZ), 03 BP 7021 Ouagadougou 03, Burkina Faso

Article Info:

Article History:

Received 27 June 2025
Reviewed 10 August 2025
Accepted 02 Sep 2025
Published 15 Sep 2025

Cite this article as:

Zongo MS, Zongo L, Ouedraogo MW, Ouedraogo S, Canfua RR, Lange H, Kabore L, Traore WFP, Lengane YTM, Bembamba DPW, Tiendrebeogo AF, Kabre E, Formulation of Functional Food Supplements: Case Study of Manufacturing Process Optimization at *'Sarepta Production'*, Burkina Faso, Journal of Drug Delivery and Therapeutics. 2025; 15(9):92-103
DOI: http://dx.doi.org/10.22270/jddt.v15i9.7383

*For Correspondence:

Luc ZONGO (+226) 52135507 frereluczong@yahoo.fr

1. Hôpital Saint Camillus de Ouagadougou (HOSCO), 09 BP 444 Ouagadougou 09, Ouagadougou, Burkina Faso.
2. Faculté des Sciences de Santé, Université Saint Thomas d'Aquin (USTA), 06 BP 10212 Ouagadougou 06, Burkina Faso.
3. Centre de Recherche Biomoléculaire Pietro Annigoni (CERBA) 01 BP 216 Ouagadougou 01. Burkina Faso.

Abstract

Introduction: In the context of promoting local resources and achieving food sovereignty, plant-based food supplements play a key role. However, their production often remains artisanal, making them prone to contamination and quality inconsistency.

Objective: This study aimed to harmonize and standardize the manufacturing practices of four dietary supplements produced at the "Sarepta Production" unit in Ouagadougou, Burkina Faso, by integrating Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP).

Methodology: Standard Operating Procedures (SOPs) were developed for each stage of the production process. Microbiological analyses were carried out on three successive batches at Agence Nationale pour la Sécurité Sanitaire de l'Environnement, de l'Alimentation, du Travail et des produits de santé (ANSSEAT) using standards established by the International Organization for Standardization (ISO standards) to assess sanitary quality.

Results and Discussion: The results showed a progressive reduction in total aerobic mesophilic flora, yeasts, molds, and thermotolerant coliforms across the three production cycles. No pathogenic microorganisms like Salmonella, *E. coli*, or *S. aureus* were detected. The implementation of GMP, GHP, and Hazard Analysis and Critical Control Points (HACCP) principles enabled effective control of critical points, such as raw material reception, mixing, packaging, and storage.

Conclusion: This study demonstrates that strict integration of hygiene and quality standards within small-scale food supplement manufacturing units significantly improves microbiological safety and consumer acceptability. It offers a reproducible model for other local food initiatives in sub-Saharan Africa in general and in Burkina Faso in particular.

Keywords: Food Supplements, Good Manufacturing Practices, Microbiological Quality, Harmonization, Local Production, Critical Control Points.

1. Introduction

Over 2,500 years ago, Hippocrates proclaimed: 'Let food be thy medicine and medicine be thy food.' This statement, from the Father of Western Medicine, highlights the fundamental role of nutrition in the promotion of health and the prevention of disease.[1–7] Indeed, the relationship between diet and human health has been consistently substantiated by robust scientific evidence.[3,5,8–12] It is well known that a balanced diet is one of the essential pillars of public health.[13]

In addition, a balanced and healthful diets contribute significantly to both immediate and long-term well-being, in the management of numerous health issues.[1] Thus, diet plays a fundamental role in maintaining health and preventing disease. Moreover, nutraceuticals are at the interface between nutrition and pharmacology and paves the way for seeking new therapeutic alternatives for the prevention of nutrition-related diseases.[14–20]

Food supplements, defined as concentrated sources of nutrients such as vitamins and minerals, are consumed to reach the normal diet and guarantee adequate intake of specific components over a defined period.[14] However, the fundamental challenge is the absence of global consensus in regulating the use of category of products known variously as dietary supplements, natural health products, complementary medicines or food supplements in different countries.[21] Another important challenge is how to harmonize and standardize these food supplements production practices.

Aside from rigorously upholding the cornerstone principle of *primum non nocere* in every aspect of human health management, it is imperative that food supplement manufacturing be both harmonized and standardized. Therefore, by aligning manufacturing protocols across regions and enforcing uniform specifications for raw materials, processing methods, dosage forms, labelling, and stability testing, manufacturers will minimize variability, prevent contamination, and reduce the risk of adverse interactions. In this way, harmonization and standardization serve as the practical embodiment of the *primum non nocere*, translating the ethical imperative of "first, do no harm" into concrete measures that protect public health. Hence, harmonization and standardization are mandatory tools in the quality control process.[22]

Thus, the implementation of consistent, internationally recognized production and quality-control standards, such as Good Manufacturing Practices (GMP), and relevant pharmacopeial monographs, can ensure that supplements not only comply with regulatory requirements, but also reliably safeguard consumer safety and well-being. In this same spirit, and in order to improve Burkina Faso's evolution toward genuine food sovereignty, there is a growing emphasis on the valorisation and on-site processing of local agri-food products,[23,24] for instance ginger bread cookies and candies and moringa capsules.[25,26]

The dietary supplements defined as foodstuffs have the purpose to supply the normal diet and they are a concentrated source of nutrients.[27–29] The ingredients constituting food supplements can be plant compounds substances with a nutritional or physiological effect additives, flavourings and processing aids.[30–34] Therefore, in the manufacturing process of food supplements, the selected ingredients are integrated into the excipients. Then, the homogeneous mixture obtained is presented in a galenic form and marketed with the opinion of the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF).

This manufacturing process should be precise and enriched at each step by quality controls.[30,35,36] In fact, when coupled with harmonized, standardized manufacturing practices *in-situ* processing can ensure that locally produced foods and supplements meet rigorous safety and quality benchmarks. However, the harmonization and standardization of the production of Dietary supplements remain a major challenge worldwide and in Burkina Faso in particular. Therefore, the main objective of this work is the implementation of a harmonization and standardization procedure in order to optimize the manufacturing practices of four food supplements in the production unit called 'Sarepta Production' in Ouagadougou, Burkina Faso.

2. MATERIALS AND METHODOLOGY

The production of food supplements was performed at 'Sarepta Production', a production unit in Burkina Faso, created in 2019, for the promotion of natural products, specializing in the design, processing and enhancement of plant-based products. The microbiological tests of the finished products obtained were carried out at the Directorate of Food Control and Applied Nutrition (DCANA), of the National Agency for the Health Safety of the Environment, Food and Health Products (ANSSEAT).

Laboratory Materials and Equipment

The laboratory was equipped with precision weighing tools, production and sterilization equipment (water baths, autoclave, ovens), refrigeration units, and quality control instruments (pH meter, colony counter, laminar flow hoods). It also includes tools for supplement preparation (grinders, mixers, packaging devices) and essential glassware for microbiological procedures, ensuring accurate, sterile, and controlled experimental conditions.

Study Methodology

Protocols and Processes of Dietary Supplements

This involved the writing and development of protocols and procedures for the manufacture and harmonization of production practices for the four food supplements *i.e.*, Tonus Powder, Moringa Nutri Plus Energy, Moringa Nutri Mix with *Parkia Biglobosa* (Soumbala) Seeds and Ginger Sweetener, at *'Sarepta Production'*, according to GMP and GHP guidelines.

Powder production process

The production of powders for the manufacturing of food supplements was carried out using processes written within the *'Sarepta Production'* unit. The main steps of the production process are reception of the raw materials, storage of the powders, manufacturing, *i.e.*, drying, grinding, mixing, and sifting, awell as packaging, labelling and storage of the final products. All these steps are carried out under quality control, in order to minimize the cross contamination as well as the microbial contamination.

Preparation of culture media

Plate Count Agar (PCA) culture medium: 11.75 g of PCA is diluted in 500 mL of distilled water. The pH of the resulting solution is adjusted (pH = 7.0 ± 0.2). The solution is sterilized in an autoclave at 121°C for 15 minutes. After the autoclave, the solution is cooled in a water bath to 45°C.

Violet Crystal Neutral Red (VCBL) Bilinked Lactose Agar Culture Medium: 20.25 g of VRBL was dissolved in 500 mL of distilled water. The solution is homogenized. The pH is adjusted to 7.4 ± 0.2. The prepared solution is brought to a water bath at 45°C.

Glucose agar culture medium with yeast extract and Chloramphenicol (YGC): 20.05 g of YGC was dissolved in 500 mL of distilled water and then sterilized in an autoclave at 121°C for 15 min until completely dissolved. The pH is adjusted to 5.6 ± 0.2.

Microbiological Analytical Methods

The germs tested and the analytical methods employed are summarized as follows. Total Aerobic Mesophilic Flora (TMAF) were enumerated according to the NF ISO 4833:1991 standard using Plate Count Agar (PCA), with incubation at 30°C for 72 hours. Yeasts and molds were assessed following the NF ISO 7954:1988 protocol, utilizing Yeast Glucose Chloramphenicol (YGC) agar and incubated at 25°C for 5 days. Total coliforms were detected using the NF ISO 4832:1991 method on Violet Red Bile Lactose (VRBL) agar, with incubation at 37°C for 24 hours. Thermotolerant coliforms, including *Escherichia coli*, were quantified according to the NF V08-017:1980 standard, using VRBL agar at 44°C for 24 hours. For the detection of *Salmonella* spp., the NF V08-6579:2002 method was applied, involving culture on EPT, XLD, and SS media, with incubation at 37°C for 24 hours.

The abbreviations used refer to standard microbial analysis protocols: TMAF stands for Total Aerobic Mesophilic Flora; NF ISO refers to the French Standard aligned with the International Organization for Standardization; PCA is Plate Count Agar; YGC denotes Yeast Glucose Chloramphenicol; and VRBL stands for Violet Red Bile Lactose agar.

Preparation of stock solutions and decimal dilutions

- 25 g of powder was placed in a sterile bottle containing 225 ml of peptone water used as a thinner. This stock solution call Mother Solution (MS) corresponds to the 1/10 or 10^{-1} dilution according to the international standard NF ISO 6888-1: 1999. A cascade dilution is then carried out.

- 2 mL of the MS is introduced aseptically through a sterile graduated pipette into a sterile screw tube containing 18 ml of the same diluent: this dilution then corresponds to 1/100 or 10^{-2}.

- 2 mL of dilution 1/100 or 10^{-2} is then introduced into a sterile screw tube, containing 18 mL of the same diluent using a sterile graduated pipette to form the 1/1000 or 10^{-3} dilution.

- The other diluted stocks were obtained through the same process. The dilution was aimed to reduce the concentration of microorganisms as the cascade dilutions are carried out, in order to facilitate the reading of the analysis results.

Germ counts

The microorganisms were enumerated on solid media. In fact, the inoculation was done according to the method of mass inoculation. Using a sterile pipette, 1 mL of each dilution was introduced into a sterile petri dish into which approximately 15 to 20 mL of the culture medium was supercooled at 45°C; then the inoculum was homogenized and the culture medium by circular movements; the mixture was allowed to solidify at laboratory temperature. Then, the petri dishes were incubated at temperatures of 25°C, 30°C, 37°C, 44°C respectively for 24 hours and 72 hours. Incubation, reading and calculation of the number of germs were done according to the standards in force for each microorganism.

Total Mesophilic Aerobic Flora (TMAF)

The total flora, *i.e.*, mesophilic aerobic flora, was enumerated according to the international standard NF ISO 4833: 1991;[37] inoculation was done on Plate Count Agar (PCA) agar medium and the petri dishes were incubated in the oven set at 30°C for 72 hours. Colonies were counted and calculated at the end of the incubation period.

Petri dishes with a content of less than 300 colonies were used to calculate the number 'N' of microorganisms present in the sample. The calculation was made using the colonies of two successive dilutions using the following formula:

$$N = \frac{\sum C}{V(n_1 + 0,1n_2)d}$$

N: number of microorganisms per gram of product expressed by a number between 1.0 and 9.9 multiplied by 10 x (where x is the appropriate potency of 10)

ΣC: Sum of the colonies counted on all the boxes retained from the two successive dilutions

V: The volume of inoculum applied to each box

n_1 : Number of boxes retained at the first dilution

n_2 : Number of boxes retained at the second dilution

d: dilution factor corresponding to the low dilution (the first one)

Total, thermotolerant coliforms and E. coli

Total coliforms were counted according to the NF ISO 4832:1991 [37] standard and thermotolerant coliforms and *E. coli* according to the NF V08-017:1980 standard. Inoculation was done on Lactose Bilié agar medium with Violet crystal and Neutral Red (LBVN). The petri dishes were incubated in the oven at 37°C and 44°C respectively for 24 hours. Characteristic colonies were counted after the incubation period.

For the calculation of the number of microorganisms per gram of sample, the same formula was used. After the specified incubation period, boxes containing fewer than 300 colonies are retained after counting. This quantification will be used for the identification of *E. coli*. In case there are characteristic colonies.

Yeasts and molds

The international standard NF ISO 7954:1988 was used for the enumeration of yeasts and molds. Seeding was done on selective YGC medium. The petri dishes were incubated at 25°C in the oven for 5 days. At the end of the incubation period, the number of colonies was calculated. The number N of microorganisms per gram of sample was determined using the previous formula.

The search for *Salmonella* was carried out in accordance with the NF V 08-6579: 2002 standard. The MS was incubated with peptone water (EPT) at 37°C for 24 hours. Then, selective enrichment was done by transferring 0.1 mL of the resulting culture into a tube containing 10 mL of RV medium and 1 mL of the same culture into another tube containing 10 mL of KTT broth. RV medium at 42°C is incubated for 24 hours and KTT broth at 37°C for 24 hours.

From the culture obtained in the RV medium after incubation of 24 hours:

- The inoculation was done with a handle on the surface of a box of the first selective medium XLD;
- The same operation was carried out with the second selective medium Hecktoen.

From the culture obtained in the KTT broth, the operations described above are repeated. The cans are incubated at 37°C for 24 hours.

At the end of the incubation, the presence of characteristic colonies of *Salmonella* is sought, identifying these colonies by their black colour.

Criteria for Interpreting Microbiological Test Results

The criteria for the microbiological assessment of spices, condiments and similar products were used by default given the compositional similarities.[38]

The interpretation of microbiological test results was conducted based on the criteria established by the National Center for Studies and Recommendations on Nutrition and Food (CNERNA, 2012). According to these standards, Total Aerobic Mesophilic Flora (TMAF) are considered satisfactory when their count is less than 5×10^5 CFU/g, acceptable when between 5×10^5 and 5×10^6 CFU/g, and unsatisfactory when exceeding 5×10^6 CFU/g. For yeasts and molds, results are deemed satisfactory if the count is below 10^5 CFU/g, acceptable between 10^5 and 10^6 CFU/g, and unsatisfactory above 10^6 CFU/g.

Thermotolerant coliforms are interpreted as satisfactory if below 10^2 CFU/g, acceptable between 10^2 and 10^3 CFU/g, and unsatisfactory above 10^3 CFU/g. In the case of *Escherichia coli* (*E. coli*), levels are satisfactory below 10^3 CFU/g, acceptable between 10^3 and 10^4 CFU/g, and unsatisfactory above 10^4 CFU/g.

Regarding *Salmonella spp.*, their absence in 25 grams of sample indicates a satisfactory result, while their presence in 25 grams renders the sample unsatisfactory; no acceptable intermediate level is defined.

Manufacturing Process

Food Supplement General Manufacturing Process

Four different food supplements were chosen for this study: Tonus Powder, Moringa Nutri Plus Energy CR, Moringa Nutri Mix with *Parkia Biglobosa* (Soumbala) Seeds, and Ginger Sweetener. The composition and appearance of the various supplements is shown in Figure 1.

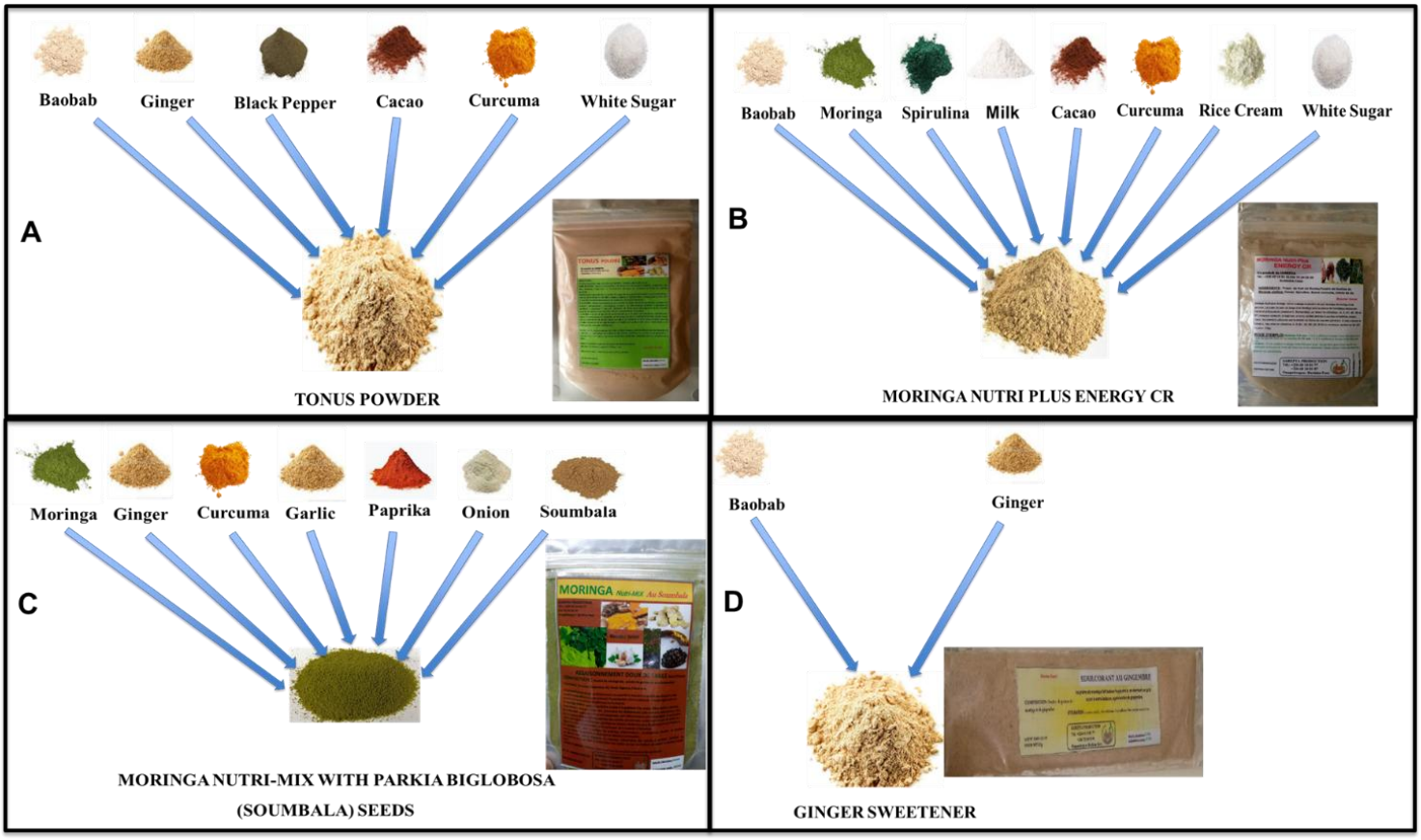

Figure 1: Physical characteristics of the raw materials and finished products of Tonus Powder (A), Moringa Nutri Plus Energy CR (B), Moringa Nutri Mix with *Parkia Biglobosa* (Soumbala) Seeds (C), and Ginger Sweetener (D).

Figure 2 is a schematic representation of the different steps of the production of the four chosen food supplement preparations.

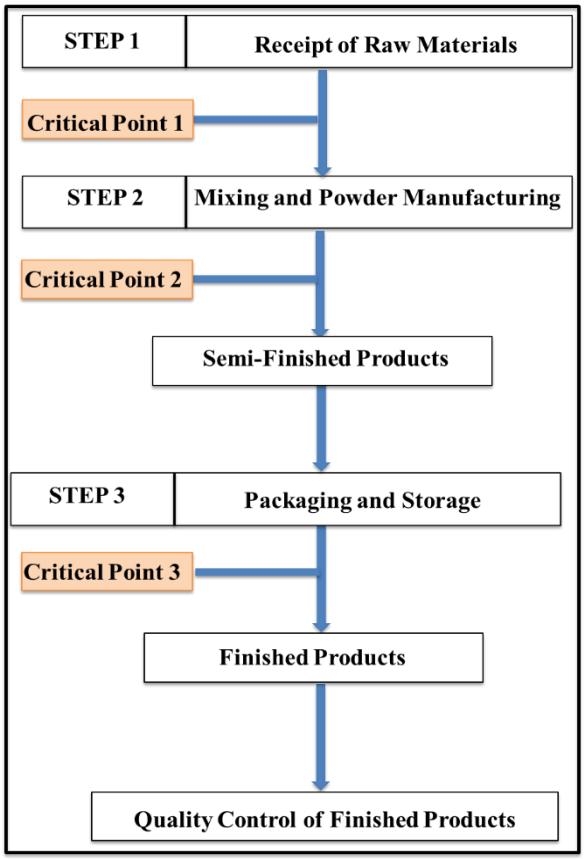

Figure 2: Dietary supplement manufacturing diagram.

Specific Manufacturing Process

Figure 3 and **Figure 4** represent the specific steps of the production of Tonus Powder **Figure 3** (**A**), Moringa Nutri Plus Energy CR **Figure 3** (**B**), Moringa Nutri Mix with *Parkia Biglobosa* (Soumbala) Seeds **Figure 4** (**A**)and Ginger Sweetener **Figure 4** (**B**).

The food supplement "Tonus Powder" was made using six ingredients *i.e.,*baobab (*Adansonia digitata*) pulp powder, ginger (*Zingiber officiale*) root power, black peper (*Piper nigrum*) powder, cocoa powder (*Theobroma cacao L.*), turmeric (*Curcuma longa L.*) powder and cane, white granulated sugar (sucrose) from qualified suppliers. The manufacturing process is shown in **Figure 3 (A)**. It results from the mixing of these different ingredients according to the defined proportions. This production process consists of three main steps, such as weighing, which takes approximately 10 minutes (based on an average of 2 minutes per ingredient); mixing, which requires 5 minutes to ensure homogeneity; and sieving, which takes about 3 minutes to achieve a uniform particle size.

"Moringa Nutri Plus Energy CR" is a food supplement consisting of a mixture of eight elements, *i.e.,*baobab (*Adansonia digitata*) pulp powder, moringa (*Moringa oleifera Lam*.) leaf powder, Spirulina (*Spirulina platensis*) powder, milk (whole milk) powder, cocoa powder (*Theobroma cacao L.*), turmeric (*Curcuma longa L.*) powder, cream of rice (*Oryza sativa L.*) and cane, white granulated sugar (sucrose) from qualified suppliers. The manufacturing process shown in **Figure 3 (B)** results in a dry mixture of a homogeneous powder. This manufacturing process involves three main steps: weighing, which takes approximately 16 minutes based on an average of 2 minutes per ingredient; mixing, which lasts 5 minutes to ensure a homogeneous blend; and sieving, which requires about 3 minutes to obtain a uniform powder consistency.

"Moringa Nutri-Mix with *Parkia Biglobosa* (Soumbala) Seeds" is a food supplement based containing the following ingredients, moringa (*Moringa oleifera Lam*.) leaf powder, ginger (*Zingiber officiale*) root power, turmeric (*Curcuma longa L.*) powder, garlic (*Allium sativum L.*) powder, paprika (*Capsium annum L.)* powder, onion (Allium cepa L.) powder and soumbala (fermented African locust bean from *Parkia biglobosa*) powder from qualified suplliers. The manufacturing process shown in **Figure 4 (A)** results in a homogeneous powder from a mixture of eight ingredients. This *modus operandi* comprises six main steps: weighing, which takes approximately 15 minutes based on an average of 2 minutes per ingredient; mixing for 5 minutes to ensure uniform distribution; sieving for 3 minutes to achieve a consistent particle size; grinding, which lasts 15 minutes to obtain a fine texture; and roasting, which requires 5 minutes to enhance flavor and improve microbiological safety.

Ginger Sweetener is a dietary supplement consisting of a blend of baobab (*Adansonia digitata*) pulp powder and ginger (*Zingiber officiale*) root power from qualified suppliers. The manufacturing process is represented in **Figure 4 (B).** This production process involves four key steps: weighing, which takes approximately 4 minutes based on 2 minutes per ingredient; mixing for 5 minutes to ensure a uniform blend; drying, which is carried out over a period of 10 hours at a controlled temperature of 46 °C to reduce moisture content and ensure product stability; and sieving, which takes 5 minutes to achieve a consistent and fine powder texture.

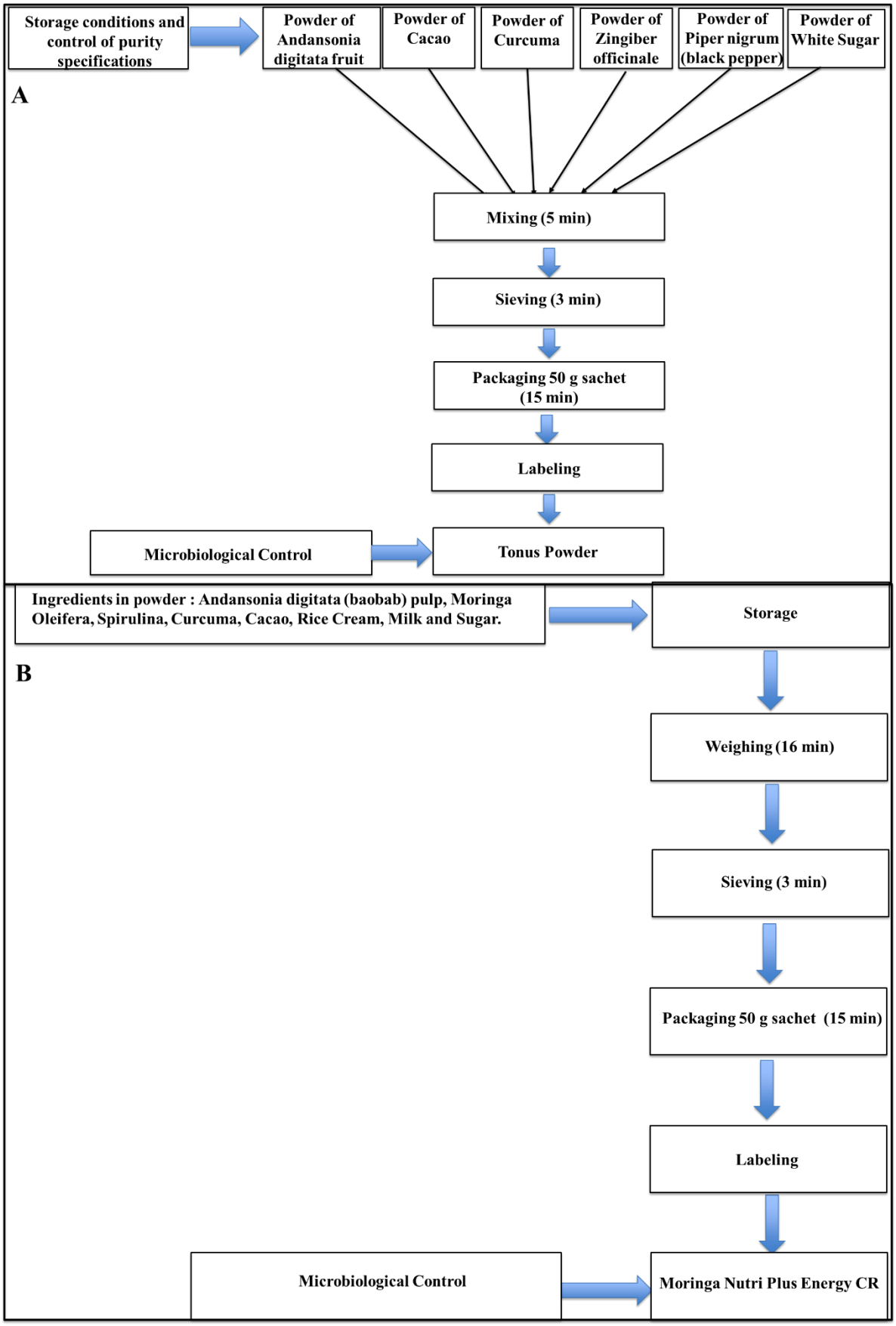

Figure 3: Diagram of the manufacturing process : Tonus Powder **(A)** and Moringa Nutri Plus Energy CR **(B)**

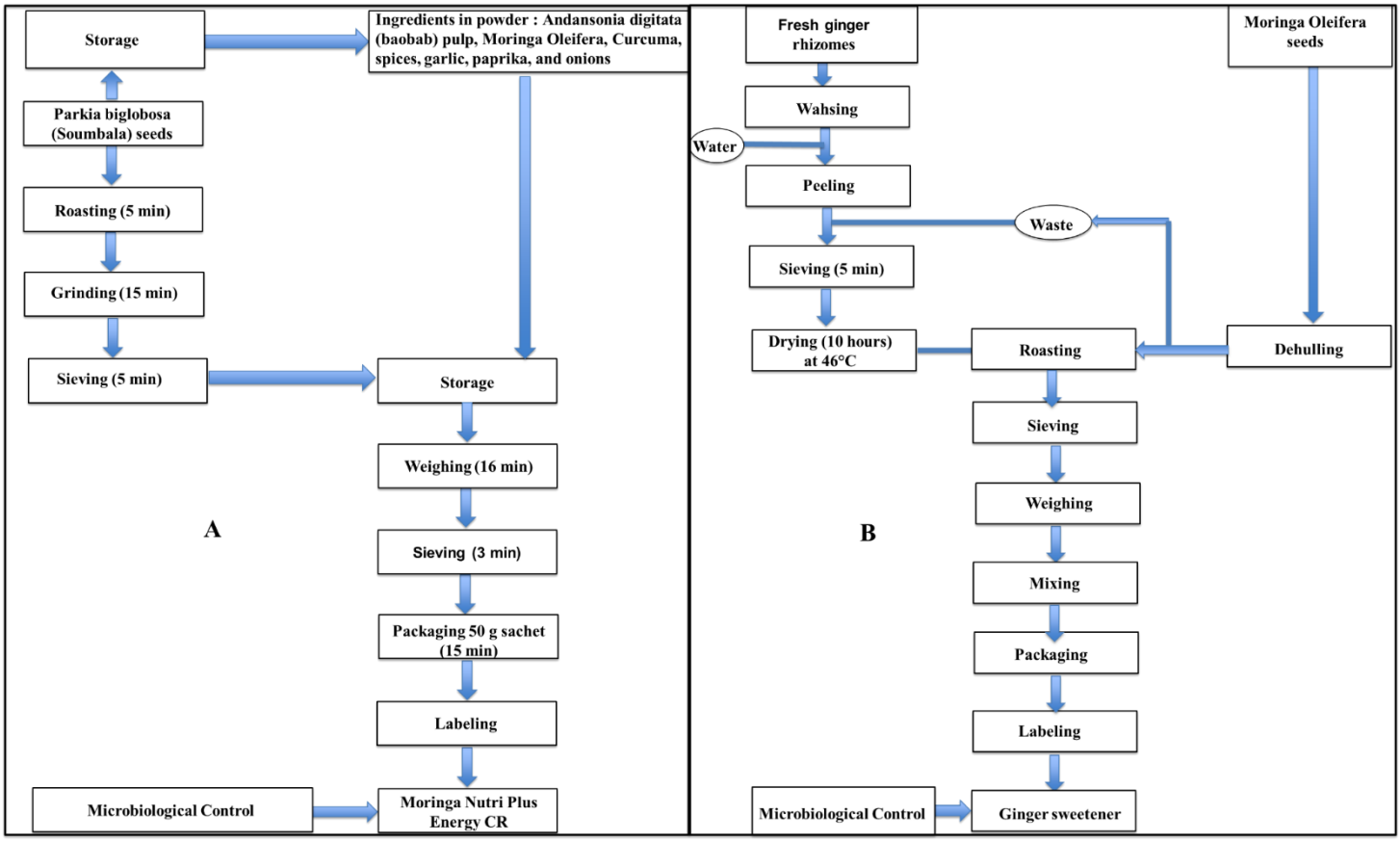

Figure 4: Diagram of the manufacturing process : Moringa Nutri Mix with *Parkia Biglobosa* (Soumbala) **(A)** Ginger Sweetener **(B).**

3. RESULTS

The manufacturing processes for each of the four food supplements have been successfully realized as described in the methodology part in **Figure 2**.

3.1 Finished products organoleptic characterisation

The organoleptic and physical characteristics of the tested extracts are described as follows. Tonus Powder presents a dark beige color with a characteristic odor, a slightly tangy taste, and a fine powdery appearance. Moringa Nutri Plus Energy CR is identified by its fine green color, a slightly characteristic odor, a slight bitterness on the palate, and a fine powdery texture. Moringa Nutri Mix with Soumbala exhibits a Veronese green color, a slightly characteristic odor, a slightly bitter taste, and a moderately fine appearance. *Ginger Sweetener* is characterized by a creamy yellow color, a very distinctive odor, a spicy taste, and a moderately fine texture. **Figure 1** indicates the physical characteristics of the raw materials and finished products.

3.2 Critical points and control measures

Table I provides a comprehensive overview of the identified critical control points (CCPs), along with the specific preventive and corrective measures established to ensure process control, product quality, and compliance with applicable regulatory standards.

Table I: Critical Control Point (CCP) and control measures.

Production Operation	Type of hazard	Control measure
Reception	Containers and raw materials arriving from outside can be a source of biological and physical contaminants.	CCP1. At the reception, the reception bins are labelled (blue, green, red), and clean; clean hands, implementation of controls upon receipt of raw materials
Mixture	This operation is carried out with small equipment. Insufficient cleaning can be a source of biological contamination.	CCP2. At this stage, users must scrupulously follow the basic rules of hygiene, namely washing and disinfecting hands and utensils thoroughly before handling.

Packaging	Moisture recovery if the seals are not watertight or if the packaging is not very resistant. Proliferation of biological contaminants	CCP3. Observe the rules of hygiene and hand cleaning before packaging and choose good quality packaging and check seams.
Storage of finished product	Moisture recovery and insect infestation. It is can be a source of biological contamination.	Keep finished products on clean shelves. Avoid storing them on the ground. Avoid storage in direct sunlight to prevent deterioration of packaging material.

3.3 Finished products microbiological characterisation

The results of the microorganism count of the samples produced at different periods are displayed in **Table II**. In addition, **Figure 4** illustrates the microbiological profile of the microorganisms investigated during the three production periods for each food supplement.

Table II: Microbiological Testing Results.

Germs Codes	FAMT CFU/g	CT CFU/g	CTh CFU/g	E. coli CFU/g	L.M CFU/g	Salmonella CFU/25g
T1	6.3×10^3	5.2×10^3	1.4×10^3	0	1.3×10^3	Absent
EG1	1.8×10^5	4.2×10^4	6.2×10^3	0	2.7×10^3	Absent
MS1	1.4×10^5	1.0×10^5	1.0×10^5	0	8.0×10	Absent
ME1	3.6×10^3	8.7×10^2	1.1×10	0	1.7×10^3	Absent
T2	4.0×10^3	0	0	0	4.9×10	Absent
EG2	7.2×10^4	6.2×10^3	8.0×10	0	1.6×10^3	Absent
MS2	1.1×10^5	1.6×10^4	1.1×10^4	0	3.1×10	Absent
ME2	2.4×10^3	1.4×10	0	0	2.8×10^2	Absent
T3	2.6×10^3	0	0	0	2.9×10	Absent
EG3	9.7×10^3	3.8×10^3	0	0	6.0×10	Absent
MS3	4.7×10^4	1.2×10^3	0	0	1.7×10	Absent
ME3	3.3×10^2	0	0	0	1.2×10^2	Absent
Standards						Absent

T: Tonus Powder; **EG**: Ginger sweetener; **MS**: Moringa nutri mix with *Parkia Biglobosa* (Soumbala) Seeds; **ME**: Moringa Nutri Plus Energy CR; **FAMT**: Total mesophilic aerobic flora; **TC**: Total coliforms; **CTh**: Thermotolerant coliforms; **E. coli**: *Escherichia coli*; **LM**: Yeasts and moulds

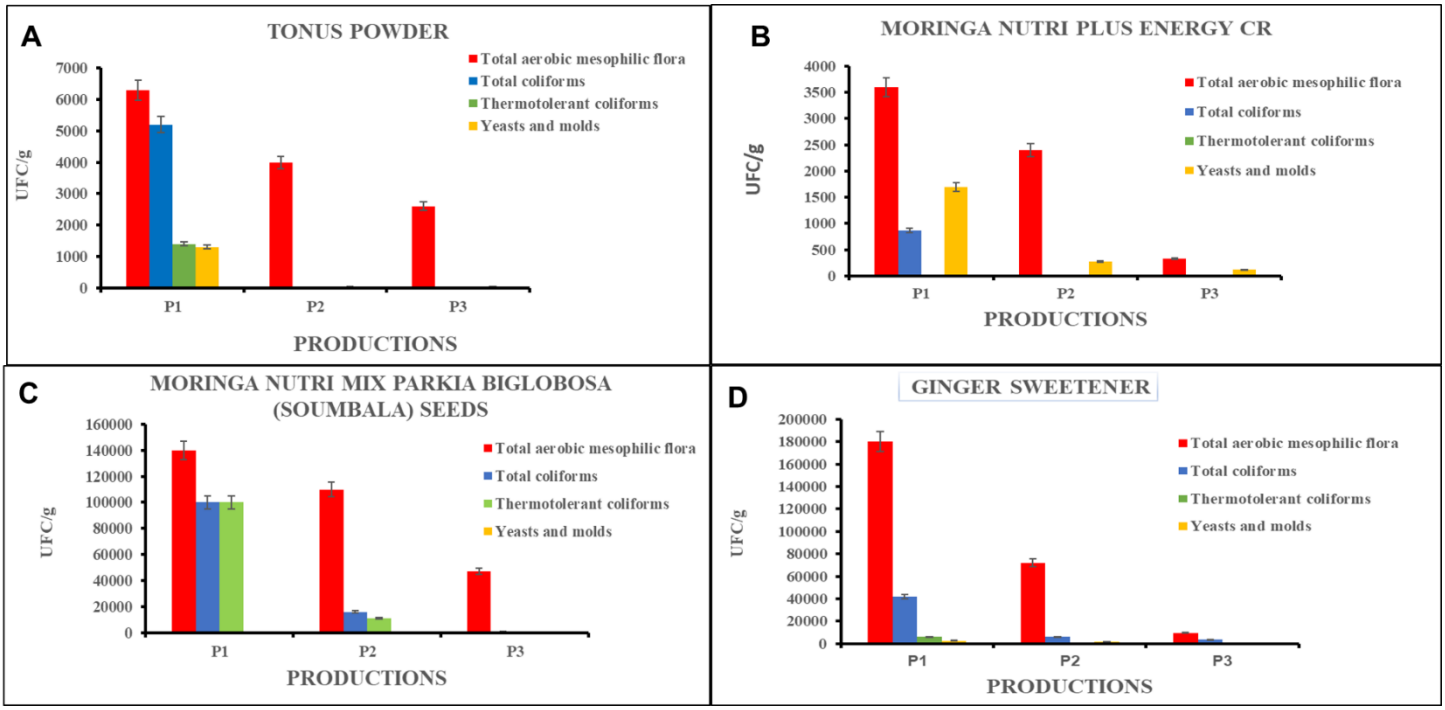

Figure 4: Tonus Powder (A)**;** Moringa Nutri Plus Energy CR (B); Moringa Nutri Mix with *Parkia Biglobosa* (Soumbala) Seeds (C); Ginger Sweetener (D).

4. DISCUSSION

The standardization of production practices implemented at the '*Sarepta Production Unit*' reflects a structured approach to ensure repeatability, traceability, and quality in the manufacture of plant-based food supplements. As noted by the French Agency for Standardization, establishing a clear documentary system with procedures and instructions is crucial to promoting effective internal communication and consistent quality outputs [39,40]

4.1 Implementation of Production Procedures

From raw material reception to packaging, each step was carried out according to West African Economic and Monetary Union (WAEMU) GMP guidelines. During the raw material reception stage, all incoming materials were carefully inspected and documented. This included identity verification, physical integrity checks, and compliance with predefined specifications, critical actions for avoiding contamination through foreign matter like sand or metal particles [41–43] Proper documentation and traceability through labeled and signed delivery records ensured full conformity to quality assurance protocols.

The transformation phase followed a rigorous sequence of operations: drying, milling, sieving, weighing, and mixing. Specific attention was paid to avoiding cross-contamination, particularly with odoriferous ingredients like *soumbala* (*Parkia biglobosa*). As recommended in GMP sheet No. 5, equipment cleaning and production scheduling were optimized to prevent flavor and microbial cross-contamination, especially given that small-scale operations often rely on shared tools.[44–46]

The packaging stage used sealed aluminum food-grade bags, with 25 g and 50 g formats. Heat sealing preserved the integrity of the product and minimized exposure to moisture, air, and light, factors that can degrade quality and promote microbial growth. All labels complied with Codex Alimentarius guidelines,[45] including the product name, composition, batch number, expiry date, and net quantity, thereby supporting consumer information and traceability.[47]

4.2 Critical Control Points and Quality Management

Two major critical control points (CCPs) were identified: physical impurities like sand in the powders and biological hazards (microbial contamination). The physical risks were addressed through meticulous cleaning of storage containers and good hygiene practices among staff, recognizing that most physical contaminants in such environments originate from human handling [48,49]. Biological risks were mitigated by training staff on GHP and targeting high-risk ingredients, such as *soumbala*, with additional decontamination steps like roasting at 100°C.

The comprehensive implementation of GHP, GMP, and HACCP system aligns with best practices observed in similar contexts [50]. Although HACCP implementation in artisanal and small-scale industries is often challenged by complexity and documentation burdens, preliminary efforts in training and awareness significantly reduce microbial and physical contamination risks.[51,52]

4.3 Microbiological Quality and Process Improvement

Microbiological analysis across three production cycles showed a progressive reduction in contamination levels, underlaying the effectiveness of the implemented process controls. The first production revealed moderate levels of FAMT, yeasts and molds, and coliforms, though all within acceptable safety limits. No pathogenic microorganisms, including *Escherichia coli* or *Salmonella spp.*, were detected.

Subsequent production runs showed an important improvement:

- ✓ FAMT decreased from 1.7×10^5 CFU/g to 3.3×10^2 CFU/g.
- ✓ Yeasts and molds dropped from 2.7×10^3 CFU/g to 1.7×10 CFU/g.
- ✓ Total and thermotolerant coliforms fell from 1.0×10^5 CFU/g to 0 CFU/g.

These results demonstrate an increasing level of microbiological control and process reliability, likely attributed to stricter hygiene procedures, enhanced staff training, and the use of HACCP-aligned preventive measures. Notably, the consistent absence of *Salmonella* and *E. coli* in all samples reinforces the sanitary integrity of the production process [53,54].

Nevertheless, the detection of coliforms and yeasts in earlier batches indicates the importance of maintaining strict hygiene protocols. Coliform presence may indicate fecal contamination, typically linked to poor personal or equipment hygiene. Meanwhile, the presence of saprophytic flora and molds can impact product stability and organoleptic properties, especially if storage conditions are suboptimal [55–57].

5. CONCLUSION

This study aimed to improve the quality and safety of plant-based food supplements produced at the '*Sarepta Production*' unit by implementing standardized manufacturing practices. Drawing on GMP and GHP, the team developed and applied Standard Operating Procedures to enhance process consistency and reproducibility.

Microbiological assessments conducted on three successive production batches demonstrated an important decline in total microbial load, coliforms, and fungal contaminants (yeasts and molds), with no detection of pathogenic microorganisms such as *Escherichia coli*, *Salmonella* spp., or *Staphylococcus aureus*. These results highlight the effectiveness of integrating GHP, GMP, and HACCP principles in improving both the microbiological safety and the organoleptic properties of locally manufactured plant-based supplements.

The observed improvements were attributed to a continuous process of optimization and the systematic

application of HACCP for identifying and controlling critical points. The study thereby contributed to the formalization of structured manufacturing protocols and reinforced the importance of documentation, personnel training, and preventive quality strategies. These outcomes are consistent with international recommendations, which emphasize that the success of quality assurance systems bases on the foundation of strong hygienic practices prior to the full deployment of advanced tools such as HACCP.

Conflict of Interest: The authors declare no potential conflict of interest concerning the contents, authorship, and/or publication of this article.

Author Contributions: All authors have equal contributions in the preparation of the manuscript and compilation.

Source of Support: Nil

Informed Consent Statement: Not applicable.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Ethical approval: Not applicable.

REFERENCES

[1] Bleich SN, Jones-Smith J, Wolfson JA, Zhu X, Story M. The Complex Relationship Between Diet And Health. Health Aff (Millwood) 2015;34:1813-20. https://doi.org/10.1377/hlthaff.2015.0606 PMid:26526238

[2] Rautiainen S, Manson JE, Lichtenstein AH, Sesso HD. Dietary supplements and disease prevention-a global overview. Nat Rev Endocrinol 2016;12:407-20. https://doi.org/10.1038/nrendo.2016.54 PMid:27150288

[3] Bailey RL, Gahche JJ, Miller PE, Thomas PR, Dwyer JT. Why US adults use dietary supplements. JAMA Intern Med 2013;173:355-61. https://doi.org/10.1001/jamainternmed.2013.2299 PMid:23381623

[4] Yeh GY, Eisenberg DM, Kaptchuk TJ, Phillips RS. Systematic review of herbs and dietary supplements for glycemic control in diabetes. Diabetes Care 2003;26:1277-94. https://doi.org/10.2337/diacare.26.4.1277 PMid:12663610

[5] Pittler MH, Ernst E. Dietary supplements for body-weight reduction: a systematic review. Am J Clin Nutr 2004;79:529-36. https://doi.org/10.1093/ajcn/79.4.529 PMid:15051593

[6] Hathcock J. Dietary supplements: how they are used and regulated. J Nutr 2001;131:1114S-1117S. https://doi.org/10.1093/jn/131.3.1114S PMid:11238828

[7] Geller AI, Shehab N, Weidle NJ, Lovegrove MC, Wolpert BJ, Timbo BB, et al. Emergency Department Visits for Adverse Events Related to Dietary Supplements. N Engl J Med 2015;373:1531-40. https://doi.org/10.1056/NEJMsa1504267 PMid:26465986 PMCid:PMC6196363

[8] Mayer J. Toward a National Nutrition Policy. Science 1972;176:237-41. https://doi.org/10.1126/science.176.4032.237 PMid:5019776

[9] Gentile CL, Weir TL. The gut microbiota at the intersection of diet and human health. Science 2018;362:776-80. https://doi.org/10.1126/science.aau5812 PMid:30442802

[10] Cotillard A, Kennedy SP, Kong LC, Prifti E, Pons N, Le Chatelier E, et al. Dietary intervention impact on gut microbial gene richness. Nature 2013;500:585-8. https://doi.org/10.1038/nature12480 PMid:23985875

[11] Dehghan P, Gargari BP, Jafar-Abadi MA. Oligofructose-enriched inulin improves some inflammatory markers and metabolic endotoxemia in women with type 2 diabetes mellitus: a randomized controlled clinical trial. Nutrition 2014;30:418-23. https://doi.org/10.1016/j.nut.2013.09.005 PMid:24332524

[12] Perler BK, Friedman ES, Wu GD. The Role of the Gut Microbiota in the Relationship Between Diet and Human Health. Annu Rev Physiol 2023;85:449-68. https://doi.org/10.1146/annurev-physiol-031522-092054 PMid:36375468

[13] FARDET A, ROCK E. Vers une approche plus holistique de la nutrition. Cah Nutr Diététique 2016:81-7. https://doi.org/10.1016/j.cnd.2015.10.004

[14] Domínguez Díaz L, Fernández-Ruiz V, Cámara M. The frontier between nutrition and pharma: The international regulatory framework of functional foods, food supplements and nutraceuticals. Crit Rev Food Sci Nutr 2020;60:1738-46. https://doi.org/10.1080/10408398.2019.1592107 PMid:30924346

[15] Coppens P, Da Silva MF, Pettman S. European regulations on nutraceuticals, dietary supplements and functional foods: a framework based on safety. Toxicology 2006;221:59-74. https://doi.org/10.1016/j.tox.2005.12.022 PMid:16469424

[16] Hasler CM. Regulation of functional foods and nutraceuticals: a global perspective. John Wiley & Sons; 2005. https://doi.org/10.1002/9780470277676

[17] Santini A, Cammarata SM, Capone G, Ianaro A, Tenore GC, Pani L, et al. Nutraceuticals: opening the debate for a regulatory framework. Br J Clin Pharmacol 2018;84:659-72. https://doi.org/10.1111/bcp.13496 PMid:29433155 PMCid:PMC5867125

[18] Das A, Sen CK. Nutritional supplements and functional foods: Functional significance and global regulations. Nutraceutical Funct. Food Regul. U. S. World, Elsevier; 2014, p. 13-39. https://doi.org/10.1016/B978-0-12-405870-5.00002-5

[19] Low TY, Wong KO, Yap ALL, De Haan LHJ, Rietjens IMCM. The Regulatory Framework Across International Jurisdictions for Risks Associated with Consumption of Botanical Food Supplements. Compr Rev Food Sci Food Saf 2017;16:821-34. https://doi.org/10.1111/1541-4337.12289 PMid:33371615

[20] Keservani RK, Kesharwani RK, Vyas N, Jain S, Raghuvanshi R, Sharma AK. Nutraceutical and functional food as future food: A review. Pharm Lett 2010;2:106-16.

[21] Dwyer JT, Coates PM, Smith MJ. Dietary supplements: regulatory challenges and research resources. Nutrients 2018;10:41. https://doi.org/10.3390/nu10010041 PMid:29300341 PMCid:PMC5793269

[22] Kunle OF, Egharevba HO, Ahmadu PO. Standardization of herbal medicines-A review. Int J Biodivers Conserv 2012;4:101-12. https://doi.org/10.5897/IJBC11.163

[23] MINISTERE DE L'ENVIRONNEMENT ET DU CADRE DE VIE. Stratégie nationale de valorisation et de promotion des produits forestiers non ligneux 2010.

[24] MERLE A. ; PIOTROWSKI M. Consommer les produits alimentaires locaux: Comment et Pourquoi? 2011. https://doi.org/10.7193/DM.067.37.48

[25] DAVEZAC A. ; TAISNE A.-F. CONSOMMER LOCAL EN AFRIQUE DE L'OUEST. Batailles Consomm. Local En Afr. Ouest, 2018, p. 128.

[26] BOISVERT V. ; CARON A. Valorisation économique des ressources et nouveaux marchés. MARCHES BIODIVERSITE, n.d., p. p 196.

[27] DECRET n°2006-352. Définition des compléments alimentaires. Règlement du Parlement européen et du Conseil du 20 décembre 2006 n.d.

[28] REGLEMENT (CE) n°466/2001de la COMMISSION DU 8 MARS 2001. Fixation des teneurs maximales pour certains contaminants dans les denrées alimentaires. JO N°77 16 Mars 2001 n.d.:P. 1.

[29] MASCRET C. La réglementation des allégations santé sur les compléments alimentaires. Actual Pharm 2014;53:59-60. https://doi.org/10.1016/j.actpha.2014.09.013

[30] SYNADIET. Charte de qualité et référentiel de qualité relatifs aux compléments alimentaires. 2015.

[31] REGLEMENT 0007/2007/CM/UEMOA. La sécurité sanitaire des végétaux et des aliments dans l'UEMOA n.d.

[32] DERBRE S. Proposer des solutions efficaces et sûres en phytothérapie. Actual Pharm 2016;55:47-53. https://doi.org/10.1016/j.actpha.2016.04.010

[33] Gouvernement français. ARRETE DU 24 JUIN 2014. Etablissant la liste des plantes, autres que les champignons, dans les compléments autorisées alimentaires et les conditions de leur emploi n.d.

[34] COHEN P. Un « champ » urbain de l'alimentaire. La vente de produits liés au souci du corps et de la santé. J Anthropol Assoc Fr Anthropol 1998:29-46. https://doi.org/10.4000/jda.2667

[35] MYLLE A. Le complément alimentaire. Thèse de Pharmacie. Université Lille 2- Droit et Santé, 2012.

[36] BAILLET O. Quelle place pour le complément alimentaire dans l'arthrose à l'officine. Thèse de Pharmacie. Université Angers, 2012.

[37] ISO 4833:1991. ISO n.d. https://www.iso.org/standard/10816.html (accessed June 1, 2025).

[38] GUIRAUD J-P. Microbiologie alimentaire. Industries agroalimentaires Hygiène et Sécurité alimentaire. 2012.

[39] Hernndez A, Martro E, Matas L, Martın M, Ausina V. Assessment of in-vitro efficacy of 1% Virkon® against bacteria, fungi, viruses and spores by means of AFNOR guidelines. J Hosp Infect 2000;46:203-9. https://doi.org/10.1016/S0195-6701(00)90818-1 PMid:11073729

[40] Gaudin V, Juhel-Gaugain M, Morétain J-P, Sanders P. AFNOR validation of Premi®Test, a microbiological-based screening tube-test for the detection of antimicrobial residues in animal muscle tissue. Food Addit Contam Part A 2008;25:1451-64. https://doi.org/10.1080/02652030802429088 PMid:19680855

[41] Tumuhimbise GA, Tumwine G, Kyamuhangire W. Amaranth leaves and skimmed milk powders improve the nutritional, functional, physico-chemical and sensory properties of orange fleshed sweet potato flour. Foods 2019;8:13. https://doi.org/10.3390/foods8010013 PMid:30621137 PMCid:PMC6351925

[42] Sui W, Mu T, Sun H, Yang H. Effects of different drying methods on nutritional composition, physicochemical and functional properties of sweet potato leaves. J Food Process Preserv 2019;43:e13884. https://doi.org/10.1111/jfpp.13884

[43] Akinoso R, Lawal AI, Raji AO, Osifuwa AO. Quality characteristics of sweet potato leaves (Ipomoea batatas L.) as influenced by processing and storage conditions. Croat J Food Sci Technol 2022;14:202-9. https://doi.org/10.17508/CJFST.2022.14.2.05

[44] Organization WH. Evaluation of certain contaminants in food: ninety-third report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization; 2023.

[45] Fortin ND. Global governance of food safety: the role of the FAO, WHO, and Codex Alimentarius in regulatory harmonization. Res. Handb. Int. Food Law, Edward Elgar Publishing; 2023, p. 227-42. https://doi.org/10.4337/9781800374676.00024

[46] Fiers MW, Kleter GA, Nijland H, Peijnenburg AA, Nap JP, Van Ham RC. AllermatchTM, a webtool for the prediction of potential allergenicity according to current FAO/WHO Codex alimentarius guidelines. BMC Bioinformatics 2004;5:133. https://doi.org/10.1186/1471-2105-5-133 PMid:15373946 PMCid:PMC522748

[47] ORGANIZATION (WHO WH. General Principles of Food Hygiene 2023.

[48] Osei Mensah J, Ohene-Yankyera K, Aidoo R. Determinants of response of street food entrepreneurs in Ghana to business management training. J Agribus Dev Emerg Econ 2018;8:391-405. https://doi.org/10.1108/JADEE-01-2016-0006

[49] Osei Mensah J, Ohene-Yankyera K, Aidoo R. Constraints to growth of micro and small-scale enterprises in Ghana: a case of street food enterprises. J Dev Agric Econ 2016;8:241-50. https://doi.org/10.5897/JDAE2016-0732

[50] Goue AF, Gavriel AA, Drogui P. Optimizing The Effectiveness Of HACCP In Agri-Food SMEs. Eur Sci J 2016;12:18-32. https://doi.org/10.19044/esj.2016.v12n24p18

[51] Pradhan N, Gavali J, Waghmare N. WHO (World Health Organization) guidelines for standardization of herbal drugs. Int Ayurvedic Med J 2015;3:2238-43.

[52] Awuchi CG. HACCP, quality, and food safety management in food and agricultural systems. Cogent Food Agric 2023;9:2176280. https://doi.org/10.1080/23311932.2023.2176280

[53] Onyambu MO, Chepkwony HK, Thoithi GN, Ouya GO, Osanjo GO. Microbial quality of unregulated herbal medicinal products in Kenya. Afr J Pharmacol Ther 2013;2.

[54] Hassan KM, Njogu PM, Njuguna NM, Ndwigah SN. Microbiological contamination of herbal medicinal products marketed in Kenya for chronic diseases: A case study of Nairobi metropolis. J Herb Med 2021;29:100475. https://doi.org/10.1016/j.hermed.2021.100475

[55] Rasul MG, Yuan C, Yu K, Takaki K, Shah A. Factors influencing the nutritional composition, quality and safety of dried fishery products. Food Res 2022;6:444-66. https://doi.org/10.26656/fr.2017.6(5).730

[56] Owureku-Asare M, Oduro I, Saalia FK, Tortoe C, Ampah J, Ambrose K. Drying Characteristics and Microbiological Quality Assessment of Solar-Dried Tomato. Int J Food Sci 2022;2022:1-13. https://doi.org/10.1155/2022/2352327 PMid:36337166 PMCid:PMC9635968

[57] Oliveira DI de, Demogalski L, Dias AH, Pereira LAA, Alberti A, Los PR, et al. Traditional sour cassava starch obtained with alterations in the solar drying stage. Food Sci Technol 2020;41:319-27. https://doi.org/10.1590/fst.16120