PRODUCTION OF A NEW HERBAL TEA: A REFRESHING FOOD DRINK WITH HEALTH BENEFITS

EXECUTIVE SUMMARY

Rosell Plus is a poly-herbal tea developed from an innovative folk recipe. The ingredients of this recipe are commonly used as a food supplement or medicine in Nigeria. The recipe is made up of *Hibiscus sabdariffa, Zingiber officinal, Syzygium aromaticum, Citrus lemon.* These herbs are commonly available in local markets all round Nigeria. Preliminary benchtop studies have been conducted and results shared through peer review articles. The goal of this project is to develop and manufacture a premium quality herbal tea that provides optimal nutritional and health benefits from Nigerian herbs that will be locally and internationally accepted using cGMP compliant standards for production and quality control. This project aims to achieve this by producing standardized and validated production, quality control and stability protocols, as well as obtaining NAFDAC and trademark registrations for the product. Also, running a pilot scale-up commercial production of Roselle plus using our innovative cGMP-compliant protocols. The benefits of this project is expected to impact on the social, economic, health and general wellbeing of Nigerians in various ways. The production, characterization, stability and quality control evaluations will be carried on in NIPRD's research laboratories and NIPRD- Drug Production Unit which is a registered as NIPRD -Pharmaceutical Company Limited, under the cooperate affairs commission. The sum of forty seven million one hundred and ninety-five thousand naira only N47,195,000.00 is required to complete the project within 12 calendar moths.

INTRODUCTION

The poly-herbal tea is developed from a folk recipe used as a food supplement or therapeutic application against flu-like symptoms such as fever, dry cough, shortness of breath, respiratory distress and general wellbeing. The various herbs that make up this recipe are commonly used as spices, folk food drinks, and household remedies in some ill health conditions. Also, these herbs have individually been acclaimed by literature and traditional medicine practitioners to have nutritional and remedial properties.

PRELIMINARY RESULTS

Brew and beverages made from *Hibiscus sabdariffa* popularly known in Nigeria as zobo exist. Some exist in the market in liquid formulation and containing different ingredients. Also, numerous research works has been carried on the *H. sabdariffa* with respect to its characterization and health benefits. *Rosell Plus* is cocktail containing other herbs with folkloric as well as internationally acclaimed health benefits. The formulation of a standardized formulation of the recipe into a single safe and stable product with nutritional and synergistic health benefits in a convenient easy to use teabag that can be brewed as an infusion is a new paradigm in nutraceutical production in Nigeria.

The preliminary benchtop studies were conducted through the funding support of the Institution Based Research Grant (IBR) of the Tertiary Education Trust Fund (TETFUND) under the Kaduna State University as a staff of NIPRD on secondment to Kaduna State University in the Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmaceutical Sciences. The project was successfully completed with respect to the funding scope. Two research articles were published in peer review journals. Since then the product has been produced in small quantities and distributed for use among staff within the institute, friends and others for a token.

HYPOTHESES

Hypotheses: The scale-up commercial production of Roselle plus using cGMP-compliant protocols, and establishment of validated charcterisation, stability and quality control protocols will enhance regulatory compliance and commercial viability of the product.

Null hypothesis: The scale-up commercial production of Roselle plus using cGMP-compliant protocols, and establishment of validated charcterisation, stability and quality control protocols will not enhance the regulatory compliance and commercial viability of the product.

GOAL

To develop and manufacture a premium quality herbal tea that provides optimal nutritional and health benefits from local herbs that will be locally and Internationally accepted using cGMP compliant standards for production and quality control.

OBJECTIVES

i. To optimize the small-scale processing and production to pilot commercial scale processing and production of the poly-herbal tea.

ii. To determine and validate appropriate quality control stability protocol in line with international accepted standards.

iii. To trademark Roselle Plus.

iii. List Roselle plus with NAFDAC.

v. To scale up production of Roselle Plus to commercial distribution and evaluate the dynamics in market supply, distribution and consumption.

iv. To place Roselle Plus in the market as a high-quality commodity for trade.

INNOVATION

i. Formulation of a folk-based herbal recipe that provides effective antioxidant and general wellness advantages as tea in a manner consistent with cGMP.
ii. Establishment of validated protocols (SOPs) for the preparation, quality control, and stability evaluation of the herbal tea.

PROJECT MILESTONE

a. A fully functional pilot commercial production and packaging lines.
b. Roselle Plus Production Master File:
    i. Raw Materials, intermediates and finished product characterization
    ii. Production SOPs
    iii. Quality control SOPs
    iv. Stability testing SOPs.
c. The listing certificate with NAFDAC.
d. Trade mark registration certificate

e. Market distribution and sales vouchers.

EXPECTED OUTCOMES AND IMPACT

i. Production of a standardized poly-herbal tea with nutritional and health benefits to promote the health and wellbeing of Nigerians.
ii. Increased financial and employment opportunities for farmers producing the herbs, job opportunities for more unemployed Nigerians, marketers and distributors.
iii. Increased productivity and stimulation of phyto- economic investment.
iv. Promotion of phyto-industrial development and phyto- research and development.
v. Validated Quality control (QC) protocols that could be adopted for similar products.
vi. Value addition and strengthening of the commercial viability of raw materials especially ginger, red roselle and clove that are previously exported in the raw form without value addition..
vii. Align with Mr. President's Renewed Hope Agenda and NASENI's objectives of driving economic impact and societal well-being of Nigerians.

SPECIFIC SCOPE OF THIS PROJECT

1. Development and validation of optimized production processes, quality control and stability evaluations SOPs.
2. Optimization of production of *Roselle Plus* in line with cGMP quality assurance protocols from bench-top to commercial pilot scale.

2. Nutritional and Phytoconstituent quantification.

3. Quality Control:

i. Microbiological quality control
ii. Physico-chemical stability and limit tests
iii. Pesticide and heavy metal limit tests
iv. Shelf life determination

4. Packaging protocols

5. Commercial distribution and sales.

METHODOLOGY

Formulation of Herbal Tea

Formula

Hibiscus sabdariffa 1 g

Zingiber officinal		1 g
Syzygium aromaticum		0.25 g
Citrus lemon (juice)	add	2.5 ml.

(i) ***Preparation of* Zingiber officinale *powder***: A quantity of fresh ginger rhizomes, enough to prepare 50 kg of ginger is procured from ginger market in Kaduna Road. The rhizomes is properly cleaned and then crushed into a wet mass using a grinding machine. The wet mass is dried in a hot air oven set at 45°C. The dry mass is then pulverized and any fibrous debris in the mass is removed. The powdered material is screened through a 1 mm mesh sieve. The dry powder is further dried at 50°C. The powder is then packed in moisture-proof containers and stored in a dry, cool, and dark place until used.

(ii) **Preparation of *Hibiscus sabdariffa* powder*:*** A sufficient quantity of the dry calyces of *Hibiscus sabdariffa* is carefully processed to produce 50 kg of dry calyx powder. The dry powder is packed in a moisture-proof bag and stored in a dry, cool, and dark place until used.

(iii) **Preparation of *Syzygium aromaticum* powder*:*** Enough quantity of dry cloves of *Syzygium aromaticum* is processed to produce 10 kg of the dried powder. The dry powder is packed in a moisture-proof bag and stored in a dry, cool, and stored away from direct sunlight.

(iv) **Preparation of Lemon Extract**

Fresh lemon was processed from the local fruit market. The fruits were deligently washed. The fruit was then extracted with an industrial automatic jouice extractor. The extract was stored into a plastic containers and stored in a Fridge set at 2 ^{o}C until used.

Preparation of granules

Appropriate quantities of the powdered herbal materials to make a batch that corresponds to 1000 tea bags (4 g of blend per tea bag) will be transferred into a mixer and the appropriate quantities of the lemon juice added. The mass is massed and then passed through a sieve of appropriate mesh size. The granules will be dried at 50 ^{o}C in an oven. The dry granules will then be packed into a teabag filling and sealing machine, and then packed into the secondary packaging materials.

Quality Control

The quality of the products will be evaluated. The primary aim is to ensure the authenticity, purity, efficacy, and safety of raw materials and the final teabag formulation. This includes demonstrating compliance with regulatory standards set by NAFDAC for herbal and fruit infusions, as well as WHO guidelines concerning contaminants and residues. The product is subjected to analyses for organoleptic properties, particle size, pH of brew, TLC of brew, tea bag content uniformity, moisture content, and dust leak. The physical packaging properties will be compared to those of commercially available NAFDAC-approved herbal teas.

Raw materials quality control

Composite samples comprising 5-10 g of each plant ingredients per batch will be analyzed using the following tools;

i. Identity test - Authentication of each plant's raw materials (*Zingiber officinale, Hibiscus sabdariffa, Syzygium aromaticum, Citrus lemon*)
ii. Moisture content determination
iii. Examination for extraneous matter
iv. Determination of pesticide residues
v. Determination of heavy metal levels on the raw materials
vi. Microbial and mycotoxin determination
vii. Physicochemical test - validated HPLC and TLC method for gingerol, hibiscus anthocyanins, eugenol.

Finished product assay

Sampling will adopt and adhere to the Pharmacopoeial and NAFDAC standards.
Tests will include the following:

i. Identity test – Organoleptic test on the brew
ii. pH determination of the brew
iii. Marker assay - Thin Layer Chromatography fingerprint
iv. Standardization: Quantity of phytoconstituents)/per sachet
v. Weight uniformity Test
vi. Teabag infusion leaching rate

vii. Moisture content determination

viii. Packaging integrity test - Dust leak examination

Tests for Accelerated Shelf-Life Changes

An accelerated stability test protocol for shelf-life determination will be carried out. The packaged herbal tea will be stored in a stability testing cabinet set at 40 ± 2°C and 75% RH for 12 months. Samples will be collected at 0, 3, and 6 months and subjected to tests for any changes in organoleptic properties, pH of brew, TLC of brew, moisture contents and dust leak. The results will be compared to those of duplicate samples stored under ambient laboratory conditions for 12 months.

Statistics

Data obtained in the quality evaluation of the raw materials, optimization of formulation, in-process quality control, as well as the quality assessment of the different batches of the herbal tea will be analysed statistically. Data will be analysed in relation to the limits specification of the different parameters.

The various sets of data will be analysed using a suitable computer software package.

INVESTIGATORS AND ENVIRONMENT

The National Institute for Pharmaceutical Research and Development (NIPRD) is a Federal Government Parastatal under the Federal Ministry of Health. NIPRD has a viable Products Manufacturing Unit for phyto-products pilot-scale and industrial production. This manufacturing unit is registered as NIPRD Pharmaceutical Company Limited (NIPCO) registered under the Corporate Affairs Commission (CAC).

Conceptual Framework

The conceptual framework of this project is directed towards translation of the benchtop and small scale production of Rosell Plus to an pilot production for commercial distribution using validated optimized production and quality control processes. NIPRD –Pharmaceutical Company Limited (NIPCO-Ltd). The production will be carried out in NIPCO facility, while the quality control and shelf life determination will be determined in Research Departments.

cGMP protocols practiced in the NIPCO

NIPCO production facility is arranged in such a manner that will ensure the production of quality products by preventing mix-ups, and contamination during production, packaging and quality control areas through measures such as:

1. Organized arrangement of the work area such that a seamless flow of activities in a progressive coordination of activities: Separate areas for different stages of production, such as raw material storage, processing, encapsulation, and packaging, to prevent cross-contamination.
2. A one-way flow of materials and personnel to prevent mix-ups and contamination.
3. Designated points for every operation to maintain a controlled environment: such as weighing, encapsulation and packaging.
4. All containers and equipment in contact with raw materials, intermediates and finished materials are of stainless steel surfaces to prevent corrosion and facilitate cleaning.
5. Continuous regular in-process checks during every batch production to ensure product consistency and quality.

BUDGET OF EXPENDITURE

Presented is a detailed budget in relation to the activities and cost.

Activity	**Items Required**	**Cost (₦aira)**
Procurement and processing of raw materials (For 20 batches of Products)	*Hibiscus* ***sabdariffa*** *, Zingiber officinal ,Syzygium aromaticum, Citrus lemon*	3,500,000.00
	Storage Packaging for Raw materials	1, 550,000.00
	Labelling materials	350,000 .00
Extraction of Tank. (Stainless steel, Stirrer, heater and filters)	Fabrication: 2 Stainless Steel tanks with heating and string facility.	4, 000, 000.00
PACKAGING	Tea bagging machine	21, 850, 000.00
	Teabag foil	4,100 000.00

Quantification of biochemicals	Chemicals and reference samples	1, 100 000.00
Quality Control Testing	Chemicals, Column and reference samples	1, 450 000.00
Shelf-life testing • Stability testing • Expiry date determination	Climatic Stability chamber	8, 145 000.00
Institutional Administrative fee		2, 250 000.00
	Total	**N47,195,000.00**

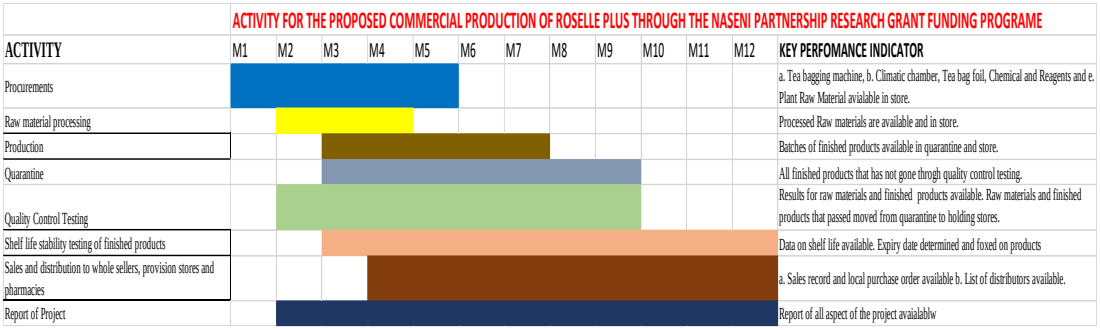
ACTIVITIES

2.3 Project Activities and Output

S/No	ACTIVITIES	KPI	DURATION (Months)
1.	Procurements	1. Tea bagging machine 2. Climatic stability chamber 3. Tea bag foils 4. Chemicals and Reagents 5. Plant Raw Materials	5
	Raw material processing	Processed Raw materials are available and in store.	3
	Production	Batches of Finished products available in quarantine and store	5
	Quality Control	Result or product quality control available and Products that passed moved from quarantine to store.	7
	Shelf life Stability testing of	Data on shelf life available. Expiry date of batches available.	6 and over.
9	Sales and distribution to whole sellers, provision stores and pharmacies	• Sales Record and Local Purchase Order available • List of Distributors available	After 4 months and continous

10	Report Writhing	Report of project available	12

Time Line: Gant Chart



RESEARCH TEAM

Name	Institution	Expertise Coordination	Qualification/Rank	Contribution to Project
Prof. Philip Builders	Department of Pharmaceutical technology	Formulation	Ph.D/ Head of Department	Principal Investigator
Dr. Tiwalade Adelakun	Department of Chemistry and Quality Control	Quality control	Ph.D/ Head of Unit	Investigator
Dr. Peters Oladosu	Department of Microbiology and Human Virology	Microbial Quality control	Ph. D/ Head of Department	Investigator
Dr. Bola Mustapha	Department of Chemistry and Quality Control	Chemical characterization and Quality control	Ph.D/ Head of Department	Investigator

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