PROPOSAL FOR THE NASENI RESEARCH COMMERCIALIZATION GRANTS PROGRAMME (NRCGP)

Project Title:

Towards Commercialization: Pilot Production of NIPRINEEM™ Tea and NIPRINEEM™ Oil from *Azadirachta indica* (Neem) in Nigeria

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Executive Summary

Neem (*Azadirachta indica*), known locally as *Dogonyaro*, is one of Nigeria's most popular medicinal plants. It is widely distributed across the country, yet its real value has hardly been tapped. For generations, people have used neem for treating infections, skin conditions, and as a natural beauty aid. Despite this, most neem trees in Nigeria remain little more than shade trees, while countries abroad are cashing in on a growing multi-billion-dollar neem products market. National Institute for Pharmaceutical Research and Development (NIPRD) in realising this gap, came up with the development of two products from Neem Plant– NIPRINEEM™ Oil and NIPRINEEM™ Tea which were developed from the seeds and leave of the plant respectively.

This project aims to upscale the production and commercialization of the two products: NIPRINEEM™ Oil and NIPRINEEM™ Tea. These will be produced to meet NAFDAC and other international acceptable standards, ensuring they are safe and affordable. NIPRINEEM™ Oil is promoted as a versatile product for skin, hair, and household use, while NIPRINEEM™ Tea is positioned as a daily wellness tea for detoxification, immunity booster and general health due to its rich antioxidant potential. With the global neem products market valued at $1.89 billion in 2023 and still growing, Nigeria can turn its local neem resources into both health benefits and economic gains.

Hence, the project will focus on scaling up the oil extraction and tea bag production facilities to pilot scale, establishing industrial scale drying facility for plant material to ensure faster drying of plant material to limit the loss of the bioactive ingredients as a result metabolic process and also to ensure availability of raw material irrespective of the season. The project also intends to establish quality control parameters for the raw materials and the finished

products and securing NAFDAC listing for both products using the developed Drug Master file.

Beyond health benefits, the project is designed to create opportunities across the value chain, from farmers who supply the raw materials, to processors, distributors, and retailers. By building local capacity for standardized production, Nigeria can reduce dependence on imported herbal products, open new export opportunities, and generate jobs.

Within the timeline of two years, NIPRINEEM^{TM} oil and NIPRINEEM^{TM} tea are expected to be lunched in attractive, ready-for-market packaging, backed by the scientific data required for regulatory approval. This project will also generate contextual processing protocols (CPP) that investors can adopt for scaling up, serve as a Hub for plant material drying and processing, and training farmers and TMPs on scaling up on production of medicinal plant products.

Ultimately, this project aligns with Nigeria's goals of healthcare improvement, economic diversification, and promotion of locally sourced alternatives to imported herbal products.

Introduction

According to the World Health Organisation (WHO), Traditional Medicine (TM) is based on theories, beliefs, experiences of different cultures applied in the prevention, diagnosis and/or treatment of illnesses. TM provides an important healthcare service in resource-poor nations. In Africa and India, it accounts for about 90% and 70% patronage respectively, while it is 40% in China (WHO, 2003). Developed countries such as the United States have experienced an increased use of herbal medicines for over the two decades (Hawks *et al*., 2021). Herbal remedies are perceived to be cheap, natural, safe and accessible. In addition, they are easier to develop into dosage formulations and can be administered whole, as teas, syrups, oils, creams, ointments, capsules, tablets, etc.

The National Institute for Pharmaceutical Research and Development (NIPRD) was established in 1989 and saddled with the primary responsibility of research, development and commercialization of pharmaceutical raw materials, drugs, phytomedicines and biological products from Nigeria's indigenous bioresources towards a sustainable access to safe, affordable and quality healthcare for the populace. In answering to this mandate, NIPRD among several products developed from Nigeria's plant resources, developed NIPRINEEM^{TM} Tea and NIPRINEEM^{TM} Oil (Figures 1 and 2) from the Neem plant, *Azadirachta indica*'s

leaves and seed respectively. Neem plant also known as “Dogonyaro”, Indian lilac, wonder tree, village dispensary, belongs to the family Meliaceae and it grows rapidly to a great height and yields fruits and flowers in season. It is native to India but also grows in the tropics and is widely known for its medicinal properties right from ancient times (Kharawar *et al*., 2020: Burkill, 1985). All morphological parts of the plant (leaves, roots, bark, fruit, seeds and flower) have been shown to possess medicinal activities hence the popularity of the plant (Mehnaz *et al*., 2024). It is commonly used as an antimalarial, antimicrobial, antiseptic, anti-inflammatory and, its effects on the skin, made it a well-known beauty agent. The Neem products available in the market include: seed cake (manure), oil, powder, hair products, skin products, oral hygiene products, insect repellents, gel, tea, spray, soap, candles, incense sticks and medicines (Chatterjee *et al*., 2023: Raju *et al*.,2019: Subbalakshmi *et al*., 2012).

Figure 1: NIPRINEEM Tea

Figure 2: NIPRINEEM OIL

Medicinal value and application of Neem Seed oil and Neem leaves tea

Neem oil:

Medicinal properties: Analgesic, Anticholinergic, Anthelminthic, Antihistaminic, Antiprotozoal, Antipyretic, Antiviral, Bactericidal, Contraceptive, Fungicidal, Insecticidal, Insect repellent, Veterinary medicine (Oyege *et al*., 2025; Chaudhary *et al*., 2021; Hao *et.al.,* 2014).

Technical: Cosmetics, Hair oils, Lubricants, Propellants, Shampoos, Soaps, Tooth pastes. Neem hair oil has proved its importance in treatment of hair fall, dandruff, lice and early greying of hairs (Ni Putu *et al*., 2024; Jay, 2019; Staughton, 2018).

An *in-vivo* study demonstrated the 100% efficacy of neem oil in preventing pregnancy when used as a vaginal lubricant prior to coitus (Jacobson, 1995).

Leaves:

Medicinal properties: Antidermatic, Antifungal, Anticlotting agent, Anthelminthic, Antituberculosis, Antitumour, Antiseptic, Antiviral, Contraceptive, Cosmetic, Fertilizer, Insecticides, Nematicidal, Insect repellent (Li *et al.,* 2025, Dani *et al*., 2025; Ngo *et al.,* 2017; Nweke and Ibiam, 2012).

Consuming raw neem leaves or neem leaf powder help in eradicating toxins from the blood (Barnes *et al*., 2008). This is one of the greatest benefits of neem tree.

The Neem plant is widely distributed in Nigeria especially in the northern part of the country. It thrives well in all tropical and subtropical regions and can tolerate high temperature of even up to 50 to 52^{o}C. Neem can grow in different types of soil but thrives best in well drained, deep and sandy soils, and can easily be propagated using its seeds, stem and root cuttings. It starts fruiting after 3 – 5 years, and it can survive for up to 200 or 300 years and it is seldom leafless. The shade it imparts throughout the year is known to be cooler than any other tree, and devoid of bugs or insects because of its unique pest control properties. Neem plant also helps to increase soil fertility by neutralizing the acidity (Chukwuma *et al.,* 2023). A lot of scientific studies have been carried out nationally and globally on *Azadirachta indica* (Dodo *et al*., 2025; Tufail *et al*., 2025; Bolaji *et al*., 2024; Chaudhary *et al*., 2021). Neem plant has however, not been fully explored for product development and commercialization in Nigeria.

The global neem extract market including oils, powders, tea etc. was valued at $1.89 billion in 2023, and is projected to grow significantly over the next several years (Grand View Research, 2023). This figure represents a huge potential for foreign exchange earning into Nigeria against the backdrop of global economic crises. The development and commercialization of products from Neem plant will not only impact positively on the national healthcare delivery system and generally improve quality of life, it will also contribute to the diversification of the economy, generate employment opportunities and generate foreign exchange for the country.

Hence, the NIPRD's NIPRINEEM^{TM} Tea and NIPRINEEM^{TM} Oil which were developed in the year 2021 was in attempt to key into the vast market available for Neem Products globally. The two products already obtained trademark and laboratory analysis carried out for the Drug master file towards listing with NAFDAC. NIPRINEEM^{TM} Tea produced from neem leaves is indicated for promotion of overall good health and improved immunity based on its antioxidant properties (Figure 1), while NIPRINEEM^{TM} Oil from Neem seeds is indicated for topical use for skin conditions and cosmetic purpose (Figure 2). The NIPRINEEM^{TM} products safety profile were within the acceptable standard for medicinal products (Adigwe *et.al*, 2021). And their comparative analysis with known brands of Neem products in the market were also highlighted in the work of Adigwe *et.al* 2022a and Adigwe *et.al*., 2022b. This project therefore, intends to upscale the production of NIPRINEEM^{TM} Tea and NIPRINEEM^{TM} Oil from laboratory scale towards commercialization in Nigeria.

Justification:

In Nigeria, neem forms about 90% of the trees in the forestry plantations established in the 12 states within the savanna zone under the afforestation programme. It has great potential not just in medicine but also in the area of pesticides and agrochemicals. Large scale production of products from this plant is very feasible as the plant is widely distributed and cultivated. However, its' potential for value-added product development remains underexploited. With the global neem extract market valued at $1.89 billion in 2023 and rising demand for herbal products, commercializing of NIPRINEEM^{TM} Oil from Neem seeds and NIPRINEEM^{TM} Tea from Neem leaves presents an opportunity to improve healthcare delivery, support economic diversification, generate foreign exchange, and create employment in Nigeria.

The pilot production of the NIPRINEEM^{TM} Products towards commercialization is hindered by the unavailability of pilot scale production facilities for fixed oil extraction and teabag making machine. Industrial scale drying facility for plant material is also an obstacle. Post harvest process of drying of plant material within the shortest possible time ensures preservation and quality of the raw material as presence of water in the material means active metabolic activities which will lead to degradation of the material. Drying preserves the bioactive components of the plant and prevent microbial growth. It also extends the shelf life of the plant material, concentration of active compound and ensure availability of raw material for production throughout the year irrespective of the season. Industrial scale drying facility will ensure faster drying of the of large of quantity of NIPRINEEM raw materials and other plants materials for quality assurance.

Objectives:

1. To upscale NIPRINEEM^{TM} Oil by scaling up the oil extraction facility towards pilot production and commercialization.
2. To upscale NIPRINEEM^{TM} Tea by scaling up the facility for teabag production towards commercialization.
3. To generate standard quality control parameters for the raw materials and products for quality assurance of the products.
4. To establish industrial scale drying facility for plant material towards ensuring quality of plant raw material.
5. To list the products with NAFDAC after production facility upgrade.

6. To produce NIPRINEEM Tea and Oil for marketing
7. To maintain the cultivated Neem plants for production and availability of sustainable and quality raw material for commercial purpose.

Methodology

The following analyses/studies will be carried out following standard procedures as stated in the NIPRD Standard Operating Procedure (SOP) Manual and other international acceptable standards (WHO, United State Pharmacopeia (USP), British Pharmacopeia (BP), including guidelines of the ISO 9001 and ISO/IEC 17025 in which NIPRD have certification.

1. Fixed Oil Extraction Machine, Tea Bag Making Machine, Industrial Scale drying facilities:

Plant and food material drying machine: Specifications: Special multilayer belt design making material heated uniformly and continuously improving drying efficiency. Drying area: 45m^2, working temperature: 0-120ºC, Drying time: 0.1-5h, Total power: 19.2Kw, Capacity: 200kg/h

Pilot Scale tea bag making machine: Specifications:(L*W*H)1750*740*1950mm, Model no- DXDPC-169, Input power- 220V/50Hz single phase, Capacity: Packaging speed -28-50bag/min,

Fixed oil extraction machine for pilot scale: Specifications: Cold press and hot press, Capacity: Cold press and hot press oil extraction of variety of seeds and nuts such Neem seeds, Castor Seeds, Groundnuts / Peanuts / Earthnuts, Sunflower Seeds etc. with feeding capacity of 20 to 200 kg/day

- All machines will be purchase thorough a vendor or competitive procurement bidding. Some may be fabricated if possible.
- Installation and training will be done for all the purchased machines/facilities
- Test running and production of products will be done as specified by the vendor and the equipment manual and supplier.

2. Collection and processing of raw materials (Leaves and seeds) will be done following good cultivation and collection practices and WHO guideline on good collection and processing of medicinal plants (WHO, 2003, NIPRD SOP).

3. Extraction of fix oil from Neem seeds using the pilot scale extraction facility following procedures and instruction as stated in the manual will be carried out.
4. Standardization of the raw materials and products will be done following standard procedures for every batch of raw materials and products towards generating quality standard for the products. Parameters to be accessed are as follows:
    - Phytochemical analysis (Quantitative and quantitative estimation of marker compounds by HPLC, GCMS, TLC, etc.) (Adamu *et al*., 2018, NIPRD SOP)
    - Pharmacognostic and physicochemical evaluation (Organoleptic, Macroscopic and Microscopic Evaluation, ash value, extractive values, moisture content, loss on drying, etc. (Trease and Evans, 2009; NIPRD SOP)
    - Microbiological quality assessment (microbial load of the herbal tea and seed oil samples) (Adigwe *et al*., 2022; NIPRD SOP)
    - Toxicological profile of Neem tea and Oil (oral acute toxicity, oral sub-chronic and chronic toxicity, acute dermal toxicity and repeated dose dermal toxicity) (Adigwe *et al*., 2021; NIPRD SOP)
5. Formulation and stability Studies will be carried out on the products (e.g. Dosage form for tea bags, Pre formulation studies, Stability studies: pH, Specific gravity, Refractive index: Thermal stability, Moisture content, Degradation of product, Physicochemical profile, Ash content, Flow rate/angle of repose, Determination of bulk and tapped density: Carr's index and Hausner ratio, Solubility, Viscosity). (Kumadoh *et al*., 2022; NIPRD SOP)
6. Formulation and Packaging of products: the Tea will be packaged 4g in a teabag for a pack of 20 teabags while the oil will be formulated in 30mls and 50mls amber bottles with dropper.
7. Listing with NAFDAC will be done following NAFDAC approved process and procedure using the NAFDAC checklist along with the Drug master file on the products.

Table 1: Project timeline

S/N	Activity	Duration
1.	Collection and processing of raw materials	2 months
2.	Purchase and installation of Pilot Scale Fix oil extraction machine; Purchase and installation of Pilot Scale Teabag Making machine;	14 months

	Purchase and installation of Industrial scale drying facilities; Training on use of the facilities	
3.	Maintenance of Cultivated Neem plantation	15 months
4.	Extraction neem oil and	2 months
5.	Generating quality standards for raw material and products. • Phytochemical analysis (Quantitative and quantitative estimation of marker compounds by HPLC, GCMS, TLC, etc.) • Pharmacognostic and physicochemical evaluation (Organoleptic, Macroscopic and Microscopic Evaluation, ash value, extractive values, moisture content, loss on drying, etc. • Microbiological quality assessment (microbial load of the herbal tea and seed oil samples) • Toxicological profile of Neem tea and Oil (oral acute toxicity, oral sub-chronic and chronic toxicity, acute dermal toxicity and repeated dose dermal toxicity)	7 months
6.	Formulation and stability Studies (Dosage form for tea bags, Pre formulation studies, Stability studies: pH, Specific gravity, Refractive index: Thermal stability, Moisture content, Degradation of product, Physicochemical profile, Ash content, Flow rate/angle of repose, Determination of bulk and tapped density: Carr's index and Hausner ratio, Solubility, Viscosity).	2 months
7.	Production of NIPRINEEM Products.	3 months
8.	Listing with NAFDAC following NAFDAC approved process and procedure.	3 months
9.	Collation or results and report writing	2 months

- The project will take about 17 months for completion as some activities will run concurrently.

Expected outcome

1. NIPRINEEM^{TM} Tea and Oil obtaining NAFDAC approval.
2. Availability of pilot scale Fix Oil extraction and Tea bag making facilities.
3. Availability of industrial scale drying facility that could available as Hub for farmers and Traditional Medicine Practitioners (TMPs) for drying their plants materials.
4. NIPRINEEM^{TM} oil and Tea available in the market for use.
5. Contextual Processing Protocol (CPP) available for possible investors in Neem products.
6. Employment created in the value chain processes of the production (e.g cultivation, processing of raw materials, production and packing, marketing sections, etc).

Team Members

	Name	Designation/Dept	Area of Expertise
1.	Dr. Jemilat Aliyu Ibrahim	PI	Plant taxonomy/medicinal plant research
2.	Dr. Peters Oladosu	member	Microbiology
3.	Dr. Adamu Aliyu	member	Phytochemistry
4.	Dr. Lucy John-Africa	member	Pharmacology and toxicology
5.	Mr. Ibrahim Gegele	member	Pharmacognosy
6.	Pharm. Kokone Ekere	member	Pharmaceutical Technology/Raw material development

BUDGET

S/N	Activity	MATERIALS	COST ESTIMATE (₦)
1.	Collection and processing of raw materials	Collection tools, seeds, wares etc	2,000,000
2.	Industrial scale plant material drying and processing facility -Specifications: Special multilayer belt design making material heated uniformly and continuously improving drying efficiency. Drying area: 45m^2, working temperature: 0-120ºC, Drying time: 0.1-5h, Total power: 19.2Kw, Capacity: 200kg/h	Purchase, installation and training	45,000,00
3.	Maintenance of Cultivated Neem plantation	Seedlings, land preparation, weeding, manures, plantation maintenance, labourers, etc.	5,000,000
4.	Extraction neem oil	Solvents, etc	2,000,000
5.	Fix oil extraction machine for pilot scale -Specifications: Cold and hot press, Motor power - 18.5+5.5Kw+80w, - Capacity: Cold and hot press oil extraction of variety of seeds and nuts such neem seeds,	Purchase, installation and training	45,000,000

	Cotton Seeds, Groundnuts / Peanuts / Earthnuts, Sunflower Seeds etc. with feeding capacity of 20kg to 100kg/day		
6.	Pilot Scale tea bag making machine - Specifications:(L*W*H)1750*740*1950mm, Input power- 220V/50Hz single phase - Capacity: Packaging speed -28-50bag/min,	Purchase of teabag packaging and sealing machine, installation and training	45,000,000
7.	Generating quality standards for raw material and products. • Phytochemical analysis (Quantitative and quantitative estimation of marker compounds by HPLC, GCMS, TLC, etc.) • Pharmacognostic and physicochemical evaluation (Organoleptic, Macroscopic and Microscopic Evaluation, ash value, extractive values, moisture content, loss on drying, etc. • Antimicrobial screening and quality assessment (microbial load of the herbal tea and seed oil samples, susceptibility of the samples to test microorganisms, minimum inhibitory concentrations and minimum bactericidal concentration of the samples) • Toxicological profile of Neem tea and Oil (oral acute toxicity, oral sub-chronic and chronic toxicity, acute dermal toxicity and repeated dose dermal toxicity)	Solvents, reagents, glassware, culture media, standards, laboratory animals, dissecting sets, slides, etc	10,000,000
8.	Formulation and stability Studies (Dosage form for tea bags, Pre formulation studies, Stability studies: pH, Specific gravity, Refractive index: Thermal stability, Moisture content, Degradation of product, Physicochemical profile, Ash content, Flow rate/angle of repose, Determination of bulk and tapped density: Carr's index and Hausner ratio, Solubility, Viscosity).		5,000,000

9.	Production of NIPRINEEM Products.	Disposables: hand gloves, head cap, lab coats, wares, consumables, etc, bottles, teabags, packs, labels, cartons, etc	5,000,000
10.	Listing with NAFDAC following NAFDAC approved process and procedure.		1,500,000
11.	Logistics, secretariat	Stationaries, communication, transportation,	5,000,000
12.	Collation of results and report writing	Data management, analysis, report dissemination etc	2,000,000
	Subtotal		**172,500,000**
13.	Miscellaneous	5%	8,625,000
14.	Administrative charges	10% of total cost	17,250,000
	Grand total		**198,375,000**

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