FEASIBILITY STUDY REPORT FOR AISHAMIN®: A STANDARDIZED ANTIDIABETIC PHYTODRUG

Executive Summary

Project Title: Standardization, Marketing Authorization, and Commercialization of *AISHAMIN*®, a Standardized Antidiabetic Phytodrug.

Proponent: National Institute for Pharmaceutical Research and Development (NIPRD)

Business Type: Pharmaceutical Research, Development, and Commercialization.

Project Location: Lagos, Nigeria.

Estimated Project Cost: ₦300 million.

Implementation Duration: 36 months.

Expected ROI: ~65% within 3 years.

Project Concept:

AISHAMIN® is a clinically validated, NAFDAC-approved herbal antidiabetic formulation developed from indigenous medicinal plants with proven hypoglycemic effects. The product will be standardized using modern analytical techniques (HPLC/LC-MS), clinically evaluated, and produced under GMP conditions for national and regional markets. The goal is to provide a safe, affordable, and effective phytodrug for diabetes management, reducing Nigeria's dependence on imported antidiabetic medications.

1. Background and Rationale

Diabetes mellitus is one of the fastest-growing chronic diseases globally and in Nigeria.

- Over 11 million Nigerians are living with diabetes (IDF, 2024).
- Annual national expenditure on antidiabetic drugs exceeds ₦80 billion, largely spent on imports.
- Many Nigerians use herbal remedies, but most lack scientific validation and regulatory approval.

AISHAMIN® leverages traditional knowledge and scientific standardization to produce a safe, reproducible, and evidence-based phytomedicine that meets NAFDAC and WHO standards for herbal medicines.

3. Project Objectives

i. To develop and standardize an effective herbal antidiabetic formulation (AISHAMIN®).

ii. To obtain NAFDAC marketing authorization through submission of a CTD-format dossier.
iii. To establish a GMP-compliant phytopharmaceutical production facility.
iv. To commercialize AISHAMIN® nationwide and in ECOWAS markets.
v. To contribute to Nigeria's pharmaceutical self-reliance and health security.

4. Technical Feasibility

4.1 Product Description

Brand Name: AISHAMIN®

Dosage Forms:

- Capsule (500 mg standardized extract)
- Syrup (100 mL bottle for mild diabetics)
- Herbal Tea (2 g sachets)

Composition: Standardized extracts of a medicinal plant codenamed Lebaaibu.

Suspected Mechanism of Action:

- Insulin sensitization.
- Inhibition of α-glucosidase and α-amylase enzymes.
- Antioxidant activity and β-cell regeneration.

Standardization Parameters:

- Quantification of active markers.
- Chromatographic fingerprinting (HPLC/LC-MS).
- Batch-to-batch reproducibility.

4.2 Development Stages and R&D Plan

Stage	Activities	Duration	Partners
1	Ethnobotanical study & authentication	3 months	University of Lagos
2	Extraction, standardization, phytochemical profiling	3 months	NIPRD
3	Preclinical studies (toxicity, efficacy)	6 months	NIMR
4	Formulation & dosage optimization	3 months	In-house
5	Clinical evaluation (Phase I–II)	12–14 months	Teaching Hospitals

6	NAFDAC submission & marketing authorization	6 months	Regulatory Consultant

4.3 Regulatory Compliance

- Product registration under NAFDAC Herbal and Complementary Medicine Directorate.
- Dossier submission in CTD (Common Technical Document) format.
- Compliance with GMP, GACP, GCP and WHO Quality Guidelines for Herbal Medicines.
- Batch release based on validated specifications.

4.4 Production Facility Requirements

- Location: Abuja industrial cluster.
- Facilities: Extraction, drying, granulation, encapsulation, packaging units, and QC lab.
- Key Equipment: Rotary evaporator, freeze dryer, capsule filler, blister packer, HPLC, UV–Vis spectrophotometer.
- Production Capacity: 100,000 capsules/month (expandable to 500,000).

5. Market and Commercial Feasibility

5.1 Market Overview

- Diabetes prevalence rising at **~5% annually**.
- The global herbal medicine market exceeds $150 billion; Nigeria's herbal segment is growing by 7–10% CAGR.
- Increased public trust in NAFDAC-approved herbal products.

5.2 Target Market

- Hospitals and pharmacies.
- Herbal and wellness centers.
- Online health retail platforms.
- Export markets (ECOWAS and Africa under AMA framework).

5.3 Competitive Analysis

Competitor	Nature	Limitation	AISHAMIN® Advantage
Imported oral hypoglycemics	Synthetic	Expensive, side effects	Natural, affordable

Local herbal mixtures	Unstandardized	No clinical validation	NAFDAC-approved, standardized
Nutraceutical teas	Food-grade	Weak efficacy	Pharmaceutical-grade validation

5.4 Marketing Strategy

- Medical detailing and clinical advocacy.
- Partnerships with diabetes clinics and pharmacies.
- Digital campaigns targeting diabetic and pre-diabetic populations.
- Product endorsement via Diabetes Association of Nigeria.

6. Organizational and Management Structure

Board of Directors: Pharmaceutical scientists and business strategists.

Management Team:

- Managing Director / CEO
- Head, R&D and Quality
- Regulatory Affairs Manager
- Production Manager
- Marketing & Distribution Manager
- Finance & Admin Manager

Strategic Partners:

- NIPRD – analytical and preclinical testing.
- NIMR / Teaching Hospitals – clinical evaluation.
- NAFDAC – marketing authorization.
- Farmers' Cooperatives – raw material supply.

7. Financial Feasibility

7.1 Estimated Project Cost (₦ Million)

Item	Cost (₦M)
R&D, Standardization & Clinical Trials	70
GMP Facility Setup & Equipment	120
Regulatory Documentation & NAFDAC Fees	30

Marketing & Branding	25
Raw Materials & Contract Farming	25
Working Capital	30
Total Project Cost	**₦300 million**

7.2 Revenue Projections (₦ Million)

Year	Sales	Operating Cost	Net Profit	Cumulative ROI
1	180	150	30	—
2	350	210	140	47%
3	600	300	300	65%

The break-even point is between the 2nd and 3rd year.

7.3 Funding Plan

- Equity Investment: ₦150M
- Bank of Industry Loan (Health Sector Fund): ₦100M
- Grants / Technical Support: ₦50M (TETFund, NIPRD, AfDB)

8. Risk Analysis and Mitigation

Risk	Impact	Mitigation
Raw material inconsistency	High	Contract farming, GACP certification
Regulatory delays	Moderate	Early NAFDAC engagement
Market acceptance	Moderate	Physician sensitization, data publication
Counterfeiting	Medium	Tamper-proof packaging, serialization
Financial constraints	Medium	Staggered financing, partnerships

9. Economic and Social Benefits

- Reduces Nigeria's dependence on imported diabetic drugs.
- Improves the affordability of diabetes management.
- Promotes local raw material utilization and value addition.
- Generates employment and capacity building for youths and researchers.
- Strengthens Nigeria's herbal medicine innovation ecosystem.

10. Project Implementation Schedule

Phase	Activity	Duration
1	R&D and Standardization	6–9 months
2	Preclinical and Clinical Evaluation	12–14 months
3	Regulatory Submission and Approval	6 months
4	Commercial Production and Launch	3 months
Total Project Duration:	**14 months**	

11. Conclusion

The feasibility study confirms that AISHAMIN® is technically sound, commercially viable, and socially beneficial. It integrates traditional herbal knowledge with modern pharmaceutical science to produce a high-impact product with strong market potential.

With an investment of ₦300 million, National Institute for Pharmaceutical Research and Development (NIPRD) will deliver Nigeria's first scientifically standardized, NAFDAC-authorized antidiabetic phytodrug, offering a profitable and sustainable return to investors while contributing to national health and industrial growth.

Annex: Key Data Highlights

Parameter	Value
Product Name	AISHAMIN®
Indication	Type 2 Diabetes Mellitus
Estimated Project Cost	₦300 million
Expected ROI (3 years)	65%
Target Market	5–10% of national diabetic population
Production Scale	100,000–500,000 capsules/month
Implementation Period	36 months
Compliance	NAFDAC CTD, GMP, GACP, WHO Herbal Standards