Feasibility Study Plan on the Grant Proposal titled - Antimicrobial Product Development from Acacia nilotica: Preclinical Studies and Product Filing.

1. Project Overview

- **Objective:** Develop an alternative antimicrobial product from *Acacia nilotica* targeting multidrug-resistant (MDR) bacteria, especially those causing respiratory tract infections, and advance it to preclinical studies and regulatory filing.
- **Scope:** Extraction, standardization, preclinical safety and efficacy studies, capsule formulation, and regulatory submission.

2. Technical Feasibility

a. Raw Material Availability

- **Source:** *Acacia nilotica* is widely available in Nigeria; plant parts (bark, pods, leaves) will be collected from authenticated sources.
- **Sustainability:** The plant is abundant, and its cultivation can be scaled, ensuring a steady supply.

b. Process and Technology

- **Extraction & Standardization:** Use of Soxhlet apparatus, rotary evaporator, and HPLC for extraction and standardization of active compounds (gallic acid, methyl gallate, catechin).
- **Formulation:** Capsule formulation using pharmaceutical-grade excipients and semi-automatic capsule filling machines.
- **Testing:** *In vitro* antimicrobial assays, *in vivo* preclinical studies (acute and sub-chronic toxicity), and stability studies.
- **Quality Control:** Adherence to WHO and FDA guidelines for herbal medicines and botanical drugs.

c. Facilities & Equipment

- **Available:** NIPRD has biosafety cabinets, HPLC, incubators, laminar flow hoods, dissolution apparatus, etc.
- **Needed:** Some equipment (e.g., rotary evaporator, Soxhlet apparatus, capsule filling machine) are budgeted for procurement.

3. Operational Feasibility

a. Project Team

- Multidisciplinary team with expertise in microbiology, medicinal chemistry, pharmacology, toxicology, plant taxonomy, and pharmaceutical formulation.
- Clear roles and responsibilities are defined for each member.

b. Timeline

- **Total Duration:** 59 weeks (~15 months).
- **Phases:** Plant collection, extraction, preclinical studies, formulation, product development, regulatory filing, and reporting.

c. Regulatory Pathway

- **Nigeria:** Filing with NAFDAC for pre-registration.
- **International:** Compliance with WHO and FDA guidelines for herbal/botanical products.

4. Economic Feasibility

a. Budget

- **Total Estimated Cost:** ₦35,507,975.00 (Thirty-five million, five hundred and seven thousand, nine hundred and seventy-five naira).
- **Breakdown:** Raw materials, chemicals, microbial strains, equipment, preclinical studies, documentation, regulatory filing, and administrative charges.

b. Cost-Benefit Analysis

- **Benefits:** Affordable, plant-based alternative for MDR infections; potential reduction in mortality; stimulation of local economy through cultivation and processing; job creation.
- **Risks:** Potential delays in regulatory approval, variability in plant material, and unforeseen preclinical toxicity.

5. Legal and Regulatory Feasibility

- **Intellectual Property:** Plans for patent and trademark registration.
- **Compliance:** Adherence to national and international standards for herbal medicines and preclinical testing.

6. Market Feasibility

- **Need:** Rising MDR infections and limited efficacy of conventional antibiotics create a strong demand.
- **Target Users:** Healthcare providers, patients with respiratory tract infections, and the broader pharmaceutical market.
- **Competitive Advantage:** Broad-spectrum activity, low toxicity, traditional use validation, and affordability.

7. Risk Assessment

- **Technical Risks:** Variability in plant extract potency, potential for batch-to-batch inconsistency.
- **Operational Risks:** Delays in procurement, equipment failure, or staff turnover.
- **Regulatory Risks:** Changes in regulatory requirements or delays in approval.
- **Mitigation Strategies:** Standardization protocols, quality control, contingency planning, and regular team reviews.

8. Conclusion

The project is technically, operationally, and economically feasible, with a strong team, clear methodology, and robust infrastructure. The anticipated benefits—both health and socio-economic—outweigh the manageable risks. With proper execution and adherence to regulatory standards, the project is well-positioned for success and impact.