



**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL HERBAL MEDICINES
TECHNICAL INFORMATION SUBMISSION TEMPLATE (TIST)**

PLEASE NOTE ALL ASTERISKED ITEMS ARE MANDATORY

***1. GENERAL DESCRIPTION OF EACH PLANT COMPONENT
CONTAINED IN THE PRODUCT**

- a. Scientific Name with Authority and photograph
- b. Synonyms
- c. Family
- d. Vernacular Names (Hausa, Igbo, Yoruba)
- e. Common names
- f. Geographical distribution
- g. Harvesting and handling of herbal medicinal raw materials
- h. Botanical Description
- i. Plant parts used
- j. Official Plant Substitute (if any)

2. CHEMICAL CONSTITUENTS AND RECORD OF USE OF THE PLANT OR POLYHERBAL (IF MORE THAN ONE PLANT)

- a. Chemical Constituents (Literature)
- b. Herbarium Specimen
- c. *Major Uses
- d. *Other Uses
- e. *Claims Verification (Testimonials, Anecdotal)

3. IDENTIFICATION (PHYTOCHEMISTRY) AND STANDARDIZATION OF HERBAL MEDICINAL PRODUCT

- a. Organoleptic Properties
- b. Fourier Transform Infra-red Identification of plant (powder or liquid)
- c. Macroscopic Description
- d. Microscopic Description
- e. Moisture Content
- f. Extraction Method
- g. Thin Layer Chromatography (Literature or Lab Acquired)

4. PHARMACOLOGICAL PROPERTIES

- a. In Vitro Experiments (Literature or Experimental Record)
- b. In Vivo Animal Experiments (Literature or Experimental Record)

5. SAFETY DATA OF EACH PLANT COMPONENT IN THE PRODUCT

- a. Traditional Use Safety Records

- b. Acute Toxicity Literature (or Pass Down History)
- c. Sub-chronic and Chronic Toxicity (Literature or Otherwise)
- d. Reproductive Toxicity (Literature if any)
- e. Mutagenic Potentials (literature if any)
- f. Carcinogenic Potentials (literature if any)

*** 6. FORMULATION**

- g. Formula and Ingredients (Plant and Excipients/Non-active Ingredients and Properties
 - Organoleptic Properties
 - Fourier Transform Infra-red Identification of plant (powder or liquid)
 - Macroscopic and Microscopic Description
 - Moisture Content
- h. Method of Preparation/ Manufacturing Process

***7. LABELLING INFORMATION (PACKAGE INSERT/ LEAFLET)**

- i. Dosage and Frequency of Administration
- j. Route of Administration
- k. Contraindications
- l. Side Effects and Adverse Effects
- m. Pregnancy and Lactation (**Statement of exclusion**)
- n. Overdose and Antidote (if any)
- o. Drug-Herb Interaction (Record if any)
- p. Children below 12 years (**Statement of exclusion**)- **Except formulation meant for children**
- q. Storage condition

**8. HERBAL MEDICINE VIGILANCE (SAFETY MONITORING
– LITERATURE IF ANY)**

9. CLINICAL SAFETY DATA (QUOTED LITERATURE)