

Traditional Medicines Registration

Directorate of Traditional Medicines, Food Supplement & Cosmetic Evaluation

Jl. Percetakan Negara No. 23

Gedung B Public Service Building 2nd Floor

Phone/Fax: 021-4244819

E-mail: penilaianot_kos@pom.go.id

National Agency of Drug & Food Control

Republic of Indonesia

ADMINISTRATION DOCUMENT

1. Local Product

a. Unlicensed Traditional Medicines

- Certificate of Manufacturer Licensed for Traditional Medicines (TMs)
- Good Manufacturing Practices (GMP) Certificate

b. Licensed Traditional Medicines

- Certificate of Manufacturer Licensed for Licensor
- Certificate of TMs Manufacturer Licensed for Licensee
- Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Products issued by government
- Good Manufacturing Practices (GMP) Certificate of Licensee

c. Toll Manufacturing Products

- Certificate of Traditional Medicines Manufacturer Licensed for Contract giver
- Certificate of Traditional Medicines Manufacturer Licensed for Contract receiver
- Good Manufacturing Practices (GMP) Certificate of Contract receiver
- Contract Agreement

2. Imported Products

- Certificate of Manufacturer Licensed for TMs or Certificate of Importer for TMs
- Trade Business License, General Importer Identity Number, Registered Importer Certificate
- Letter of Authorization
- Good Manufacturing Practices (GMP) Certificate with 2 years last inspection data
- Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Products issued by government

TECHNICAL DOCUMENT

1. Local Product

a. Formula

- Composition: active ingredient and excipient in metric unit
- Direction of use: the direction of use, dosage, warning, precaution, duration of administration if any

b. Quality and Technology

- Manufacturing process started from raw material handling till processing of finished products
- Certificate of analysis of raw materials
- Certificate of analysis of finished products (organoleptics, physical-chemical, microbial, and heavy metal contaminant)
- Protocol and result of stability study

2. Imported Product

- Requirements are the same as local product and should attach data from manufacturer of original country
- Certificate of analysis of finished products from accredited laboratories in Indonesia (organoleptics, physical-chemical, microbial, and heavy metal contaminant)
- Toxicity test data for traditional medicines which its safety has not known from accredited Laboratories in Indonesia or country of origin.

REQUIREMENT OF STANDARDIZED HERBAL MEDICINES & PHYTOPHARMACA

1. Standardized Herbal Medicines

- Safe
- Efficacy claim supported by scientific evidence (Pre-clinical Study results)
- The raw material have been standardized

2. Phytopharmaca

- Safe
- Efficacy claim supported by scientific evidence (Pre-clinical Study results)

LABELLING

Logo of traditional medicines requires:

- Word: "JAMU"



JAMU

- Word: "STANDARDIZED HERBAL MEDICINES"



OBAT HERBAL TERSTANDAR

- Word: "FITOFARMAKA"



FITOFARMAKA

- Product Name
- Net weight or net volume
- Composition
- Logo of Jamu, Standardized Herbal Medicines, Phytopharmaca
- Names & Address of Register
- Name & Address of Register of Manufacturer/Licensor
- Register number
- Expiry date, Batch number/Production code
- Indication
- Contraindication, side effect and warning, if any
- Storage
- Other information related of safety, quality, or source of material according to provision, example Alcohol content, synthetic sweetener.