

TFDA NO.....

**THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH**

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FORM FOR REGISTRATION OF HERBAL DRUG

Date: Application Numberfor official use only)

1.0 Particulars of products

1.1 Product Name:

1.2 Pharmaceutical dosage form:
.....

1.3 Therapeutic use(s):
.....

1.4 Distribution category:

1.5 Type of container:
.....
.....
.....

1.6 Pack size(s):
.....

1.7 Shelf life.....
.....

1.8 Shelf life after first opening of container (where applicable).....

.....
1.9 Shelf life after reconstitution (where applicable).....
.....

1.10 Storage conditions:.....
.....

2.0 Particulars of applicant

Name:.....

Physical Address:

.....

Postal Address:.....

Country:

Phone:.....

Fax:.....

E-mail.....

3.0 Particulars of a responsible person (for herbal drugs to be imported only)

Name:.....

Physical address:.....

.....

Postal address:.....

.....

Phone:.....Fax:.....E-mail.....

4.0 Manufacturer and qualified person for manufacture of the herbal drugs

(a) Manufacturer

Name:.....

Physical address:.....

.....

Postal address:.....

.....

Phone:.....Fax:.....E-mail.....

(b) Qualified person:

Name:.....

.....

Qualifications:.....

.....

Address:.....

.....

Phone:.....Fax:.....E-mail.....

5.0 Status of registration of the product in the country of origin, authorization/registration number and date. State whether it is registered in any of the following countries: ICH/VICH countries, Australia, Canada, South Africa, Egypt, Malaysia and Zimbabwe.

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6.0 Product composition

6.1 Active ingredient(s)

SN	Name	Specification (BP, USP, etc)	Quantity used per dosage unit	Reason for inclusion

6.2 Excipients

SN	Name	Specification (BP, USP, etc)	Quantity used per dosage unit	Reason for inclusion

7. Declaration by an applicant

I, the undersigned certify that all the information in this form and accompanying documentation is correct. I further confirm that the information referred to in my application file is available for verification during GMP inspection.

I also agree that I am obliged to follow the requirements of the Tanzania Food, Drugs and Cosmetics Act 2003 which are related to herbal drugs.

Name:

Position in the company:.....

Signature:

Date:..... Official stamp:.....