APPLICATION FORM FOR REGISTRATION OF PHARMACEUTICALS

(Made under section No.53 of the Act No.2/2006)

{For official use only} Date..... Application No..... .....

PRODUCT PARTICULARS

1. Proprietary name
1.1 Name of the active ingredient(s) (International Non-proprietary Name in English)
1.2 Pharmacotherapeutic classification (Anatomic-Therapeutic Classification system)
2. Pharmaceutical Dosage form
2.1 Route of administration
2.2 Container, closure and administration devices
2.3 Package sizes..... 2.4 Shelf life..... 2.5 Shelf life (after first opening of container) ..... 2.6 Shelf life (after reconstitution)..... 2.7 Storage conditions.....
2.8 ☐ Narcotic or ☐ Psychotropic ☐ Prescription only ☐ Pharmacy only ☐ General sale ☐ Other information

3. Details of applicant (who must be the future holder of the marketing authorization/registration certificate)

Name: .....

Business Address: .....

Postal Address: .....

Country: .....

Phone: Fax: Email:

3.1 Details of a locally responsible person (who must be nominated by the applicant and submit evidence of power of attorney)

Name: .....

Business Address: .....

Country: .....

Phone: Fax: Email: -

3.2 Manufacturer(s), site(s) and authorized person(s) for the pharmaceutical dosage form

NAME (Attach WHO Certification of each)	ACTIVITY	SITE (Business Address, Phone and Country)	AUTHORIZED PERSON
			Name: Business Address:

Source (manufacturer) of Active Pharmaceutical Ingredient(s):

Name: .....

Street Address: .....

Business Address: .....

Country: .....

Phone: Fax: Email:

4. Status of marketing authorization/registration in the country of origin and authorization/registration number and date where applicable -

5. Registration status for this medicine in the SADC member states and in other countries

Registered:	Country: Date of authorization: Authorization number: Trade name:
Pending:	Country: Date of submission: Application number:
Rejected:	Country: Date of rejection: Application number: Reason for rejection:
Withdrawn (by applicant before registration)	Country: Date of withdrawal: Reason for withdrawal: Trade name:
Withdrawn (by applicant after registration)	Country: Date of withdrawal: Reason for withdrawal: Trade name:
Suspended/Revoked/Withdrawn (by competent authority)	Country: Date of withdrawal: Reason for withdrawal: Trade name:

6. Proposed indications of the product

7. Complete composition per dosage unit

Name (INN) of	Reason for inclusion	Quantity	Unit of measure	Referenced monograph
- API				
1.				
2., etc.				
- Excipients				
1.				
2., etc. -				

8. Declaration by an applicant

I, the undersigned certify that all the information in this form and all accompanying documentation is correct. I further certify that I have examined the following statements and I attest to their correctness: 1. The current edition of the WHO guideline on **"Good Manufacturing Practice for Pharmaceutical Products"**, and/or equivalent national guideline, is applied in full in all premises involved in the manufacture of this medicine.

2. The formulation per dosage form correlates with the master formula and with the batch manufacturing record.

3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record.

4. Each batch of all starting materials is either tested or certified (in accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and must comply fully with those specifications before it is released for manufacturing purposes.

5. All batches of the active pharmaceutical ingredient(s) are obtained from the source(s) specified in the accompanying documentation.

6. No batch of active pharmaceutical ingredient(s) will be used unless a copy of the batch certificate established by the manufacturer is available.

7. Each batch of the container/closure system is tested or certified against the full specifications in the accompanying documentation and complies fully with those specifications before released for the manufacturing purposes.

8. Each batch of the finished product is either tested, or certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and complies fully with release specifications before released for sale.

9. The person releasing the product is an authorized person as defined by the WHO guideline **"Good Manufacturing Practices: Authorized person – the role, functions and training"** and/or an equivalent Tanzania guideline.

10. The procedures for control of the finished product have been validated for this information. The assay method has been validated for accuracy, precision, specificity and linearity.

11. All the documentation referred to in this certificate is available for review during GMP inspection.

12. Clinical Trials were conducted in accordance with Good Clinical Practice, where applicable. –
I also agree that:

1. The holder of marketing authorization/registration certificate is obliged to follow Zanzibar Food, Drugs & Cosmetics Board requirements for handling adverse reactions of its products.

2. The holder of registration certificate is obliged to follow Zanzibar Food, Drugs & Cosmetics Board requirements for handling batch recalls of its products.

Name:.....

Qualification:.....

Position in the company:.....

Signature:.....

Date:..... **Official stamp:** -

N.B. False declaration constitutes an offence

FOR OFFICIAL USE ONLY

Fees ..... Receipt No. ....of .....,
License granted/not granted because .....
..... License No. .....

....
Date **Responsible Registration Officer Signature**

Approved by Management meeting No. .....of .....

..... **.....**
Date **Signature for Executive Director and stamp**