

This form should be dully filled in and sent to the *Director General, Tanzania Food and Drugs Authority, Off Mandela Road, Mabibo External, P. O. Box 77150, Dar es Salaam, Tanzania* together with the relevant data as prescribed in the Application Guidelines for Registration of Veterinary Medicinal Products

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

TANZANIA FOOD DRUGS AUTHORITY



**APPLICATION FORM FOR REGISTRATION OF A VETERINARY
MEDICINAL PRODUCT**

For official Use Only Application No.:..... Date Received:.....

1. Particulars of applicant

Name:.....

Physical address:.....

Postal address:.....

Telephone No.:.....Telefax No.:.....

Email:.....

Website:.....

2. Particulars of the Manufacturer(s) and Activity

Name	Physical address of Production Site	Activity
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1.
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2.
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3.
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(Attach copies of cGMP certificate from the country of origin drug Regulatory Authority local (DRA) for each site)

3. Particulars of Local Responsible Person

Name:.....

Postal

Address:.....
.....
.....

Telephone No.:..... Telefax No.:.....

E-mail:.....

Website:.....

4. Particulars of the medicinal Product

Proprietary name (Trade name).....

Approved name

(INN/Generic).....

Dosage form.....

Strength.....

Description of the product (colour, shape, size, etc)

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Commercial presentation (packaging and pack sizes applied for in which stability studies were conducted):

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Route of administration.....

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Distribution category requested (POM/OTC):

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ATC Classification:

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Country of manufacture

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Shelf life in months:.....

Storage conditions:.....

5. Pharmaceutical formula of the product in terms of unit dose:

Description of the ingredients:

Name(s)of ingredients and specification(s)	Quantity	State whether Active/excipient/other	Reason(s) for inclusion

The chemical name, molecular and structural formulae of the active ingredient(s):

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6. Specifications of Packaging material

Primary container(s):

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Secondary container(s):

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7. Current Registration Status

State the names of all countries (including the country of manufacture) where the product is registered

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If not registered in country of manufacture, give reasons

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If the drug has been rejected/refused/deferred/cancelled/withdrawn in any country or territory supply details:

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Is the product under patent?

Yes/No:.....

If yes, provide name of Patent holder:.....

Expiry date of the Patent:.....

8. Certificate of a Pharmaceutical Product (WHO type)

Submit a certificate of a pharmaceutical product WHO type (current format) together with a copy of approved product information sheet.

9. Chemistry and Pharmaceutical Data on Dosage Form

Raw material (active /inactive) specifications including manufacturing processes and analytical control procedures carried out as release requirements:

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Details of manufacturing procedures including packaging and equipment used:

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In-process controls performed:

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Final product specifications and analytical control procedures carried out as release requirements:

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Stability data based on a minimum of three batches:

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Complete batch records relating to one production batch:

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Summary of the experiments and results performed on the drug to confirm its physiological availability:

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10. Toxicology and Pharmacology

Particulars of toxicological studies done (target species, users, consumers and the environment):

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Particulars of therapeutic effects and indications:

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Particulars of clinical trials and pharmacological studies:

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For specified category of products, provide proof of field trials performed in a member state/region, endorsed by the relevant authority:

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Particulars of side effects, contraindications, etc. of the product:

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Data relating to the pharmacokinetics and bioavailability of the drug in animals, bioequivalence data for generics including full reference product details:

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Details of drug residues and withdrawal periods in species intended for human consumption:

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11. Supporting documents and materials

Samples:

Provide a minimum quantity of the product in commercial pack to conduct two sets of full analysis,

For non-pharmacopoeia products, provide a minimum of 200mg of reference standards with the corresponding Certificate of Analysis,

Product information:

Provide copies of package inserts, labels and samples of packaging materials,

Provide samples of the proposed advertising and promotional materials,

12. Declaration

I, the undersigned hereby apply for registration of the product detailed above and declare that all the information contained herein and in the annexures is correct and true.

I enclose a fee of US \$:..... Bankers Cheque

No.....

Date:.....

Signed:.....

Full name of Signatory:.....

Official designation and qualification:.....

(Official Stamp)

NB

1. The signatory shall be a person responsible for the release of the product working for and/or authorized by the applicant. The designation and qualification shall be stated.