CONFIDENTIAL **MEDICINES CONTROL AUTHORITY**

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR REGISTRATION OF A MEDICINE

(To be submitted in duplicate)

To be sent to the Director – General, Medicines Control Authority, P.O. Box UA 559, Union Avenue, Harare or to be lodged at the offices of the Director – General, Medicines Control Authority, 106 Baines Avenue, Harare.

Samples and printed matter to be forwarded by post or by other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances

Particulars of Applicant :

Name ……..

Business address ……

Postal address ……...

Telephone number ……...

Particulars of medicine:

Approved name (if any) (1) ……...

Proprietary name (Trade mark), if any (2) ……..

Title of patent (registered in terms of the Patent Act *[Chapter 202]* if any ……

Name of proprietor of patent ……

Number of Patent ……

Is the patent still in force? YES/NO*

The form in which the medicine is presented, and the colour thereof (3) ……..

Name and address of principal ……..

Name and address of manufacturer ……

……

Country of origin ……

The strength of the medicine ……..

Classification (4) ……..

Will the medicine be manufactured, partially manufactured, repacked or relabeled in Zimbabwe?

……

State who will complete the process of manufacture ……

State address at which the certificate will be kept ……

……

I enclose the fee of ……

I, the undersigned, hereby declare that all the information contained herein and in the appendices is correct and true.

Date …….. **…….**

Signature of applicant

**Delete the inapplicable*

Notes I. 2. 3 and 4

GENERAL INFORMATION

1. If no name has been allocated to the medicine by an appropriate international body, the name which has been or will be submitted for approval must be mentioned here.
2. Medicines which are not identical in composition or strength are not regarded as the same medicine, but application for registration of medicines which vary only in strength may be made on the same form.
3. The form of preparation, i.e. capsules, ear drops, emulsions, eye drops, injections, ointments, solutions, suppositories, suspensions, tablets, etc. and the colour thereof must be mentioned here.
4. The classification of the medicine as described in the Fifth Schedule of the Medicines and Allied Substances Control (General) Regulations, 1991.

APPENDIX I

Name of medicine ……...

Name of applicant ……

The form in which the medicine is presented and the colour thereof ……...

……

The following is a schedule of the —

(a) active ingredients, giving their approved names, chemical names, structural formulae, specification and quantity in a dosage unit of the medicine;

(b) inactive ingredients giving specifications and quantity and reason for inclusion, e.g., preservative, antioxidant;

(c) specification of any raw materials used in the manufacturing process and not present in the finished medicine; and

(d) specification of packaging material in immediate contact with the medicine.

Approved name	Chemical name and structural formula (1)	Quantity per dosage unit	Active or non-active	Specifications (2)	Reason for inclusion of ingredient

Specifications of additional raw material (if any) (2) used in the manufacturing process and not in the final product

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Specification of packaging material (3) ……

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NOTES

1. The chemical name must, where possible, be given in terms of the published list of an appropriate international body.
2. Reference to the following publications will, where applicable, be acceptable:
   (a) British Pharmacopoeia;
   (b) European Pharmacopoeia;
   ((c) Pharmacopoeia of the United States of America;
   (d) Pharmacopoeia of Japan;
   (e) International Pharmacopoeia;
   (f) such other works of reference as may be approved by the Authority.
3. Where no specifications for raw materials and packaging materials exist this must be mentioned.

APPENDIX II

Name of applicant ……

Name of medicine ……...

The form in which the medicine is presented and the colour thereof ……...

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(a) A summary of the manufacturing procedure ……

……...

……...

……...

(b) The analytical control procedures performed on raw materials including the microbial status where applicable.

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(c) The analytical control procedures performed during the manufacturing process

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……...

(d) The analytical control procedures used to determine the compliance with specifications

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……..

(e) The full specifications of the medicine including microbial limits ……..

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(0 Data and reasoning on which the stability of the medicine is predicted (minimum of three batches is required)

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(g) The shelf life claim ……

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(h) Copies of all records and batch data relating to a particular batch (preferably that of the sample submitted). This includes raw material analytical reports, manufacturing and packing master sheets, in process control records, final product analytical report and authorization for release and any other appropriate records. ……...

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Where appropriate, references to the publications mentioned in the notes to Appendix I, will be acceptable

APPENDIX III

Name of applicant …….. ……..

Name of medicine ……

The form in which the medicine is presented and the colour thereof …….

…… ……..

1. (a) Has the medicine been registered in the country of origin? YES/NO* [If YES a valid certificate of registration in respect of such medicine issued by the appropriate authority established for the registration of medicines in the country of origin must accompany misapplication.]
   (b) Has an application for the registration of the medicine been made in any other country? YES/NO*

   If YES, state details ……

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   (c) Has the registration of the medicine been rejected, refused, deferred or cancelled in any country? YES/NO*

   If YES, state full details …… ……

   ……...

   Do you intend to advertise the medicine? YES/NO*

   If YES, state how and give details of proposed advertising and promotional materials ……

   …… ……..

   ……..

   ……..

2. Under what category do you envisage distributing the medicine? …… …...

   ……

**Delete the inapplicable*

APPENDIX IV

Name of applicant ……

Name of medicine …… ……...

The form in which the medicine is presented and the colour thereof ……...

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(a) The following particulars refer to the toxicological trials undertaken. ……

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(b) The following particulars refer to therapeutic effects of the medicine ……

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(c) The following particulars refer to the tests which have been performed on animals regarding the efficacy of the medicine and the purposes for which it will be promoted, with special reference to the dosage and method of administration (pharmacological trials)

…… ……...

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(d) The following particulars refer to the tests which have been performed as in (c) above on humans:

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(e) The following are particulars of the purpose, mode of action, side effects, contra-indications of the medicine:

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……..

(f) The following data relating to the pharmacokinetics and the bioavailability of the medicine in humans and animals is attached.

(g) State details of medicine residue in species intended for human consumption ……

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(h) State details of withdrawal periods for species intended for human consumption

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APPENDIX V

Name of applicant ……

Name of medicine ……

The form in which the medicine is presented and the colour thereof ……

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(a) The following are references to literature about the medicine:

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(b) The attached are relevant documents concerning the medicine:

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(c) Twenty copies of the package inserts or draft package inserts and twenty labels or copies of packages are attached:

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(d) All proposed advertising and promotional material is attached:

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(e) Samples have been submitted by registered post/by hand* to the Director - General:

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*Delete the inapplicable