CONFIDENTIAL **MEDICINES CONTROL AUTHORITY**

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:031

Medicines Control Authority of Zimbabwe

APPLICATION FOR AUTHORIZATION TO CONDUCT A CLINICAL TRIAL

CLINICAL TRIAL

*(to be **submitted in triplicate**)*

1. Particulars of applicant

Individual Full names b

Date of Birth 11-03-1982

Place of Birth 11-03-1982

Qualifications b

Professional Address b

Telephone number b

Email Address baladi@yahoo.com

if company

Name of company

Registered office

Physical address

Telephone number

Position of applicant

Main field of manufacture

2. State the name of the medicine, its chemical composition, graphic and empirical formulae, animal pharmacology, toxicity and teratology as well as any clinical or field trials in humans Or animals, or any other relevant information and supply reports, if any

Name of medicine busy

Study drug a

Chemical composition **Medical Device**

3. State any adverse or possible reactions to the medicine

4. State therapeutic effects of the medicine

5. (a) Has the medicine been registered in the country of origin?

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 shall accompany this application.

if **NO** state details

(b) Have clinical trials been conducted in the country of origin?

If **YES** state details

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if **NO** give reasons why

.....

(c) Has an application for the registration of the medicine been made in any other country? .....

If **YES** state details including the date on which the application was lodged

.....

(d) Has the medicine been registered in any other country? .....

If **YES** state details

.....

(e) Has the registration tug the medicine been rejected, or refused, deferred or cancelled in any country? .....

If **YES** state details

.....

(f) What is the status of the medicine in Zimbabwe? .....

6. State the name(s), addresstes) and telephone members) and qualifications of the person(s) who will conduct the trial

Name	**Qualifications**	**Address**	**Telephone Number**
b	b	b	b

Business

7. State the name. physical address and telephone number of the institution or the places where the trial will be conducted

Name	**Physical address**	**Telephone**	**Contact person**

8. State the purpose of the trial and the reasons therefore

.....

a

.....

9. State the time period for the trial

cva

10. Description of the type of trial

Type of trial: Opened

Randomised: No

Open:

Single Blind:

Double Blind:

Parallel group:

Cross over:

Other:

if **yes** to other, specify:

If controlled, specify the comparator:

Other medicinal product(s):

Placebo:

Other:

if **yes** to other, specify:

11. Description of participants (e.g. age group of persons or animals, type or class of persons or animals, sex. etc.)

c

12. Criteria for inclusion or exclusion of participants

r

r

13. Number of participants expected to take part in the trial and a justification thereof (e.g. based on statistical considerations)

Expected Number of participants 3

Total enrolment in each site 1

Total participants worldwide 2

Justification

c

14. Administration route, dosage, dosage interval and period for the medicine beMg tested and the medicine being used as a control

15. Control groups (placebo, other therapy, etc.)

16. (a) State whether any other medicine will be Oven concomitantly.

If **YES**, state the name of the medicine

(b) State whether the person already on another medicine will be given the experimential medicine at the same time or will be taken off the medicine

17. Recording of effects: give a description of the methods of recordings and times of recordings

18. State clinical and laboratory tests, phannacokinetic analysis, etc., that are to be carried out

19. State the method of recording adverse reactions and provisions for dealing with same and other complications

fads

20. State antidote

21. State the procedure for the keeping of participant lists and participant records for each participant taking part in the trial +

22. State where the trial code will be kept and how it can be broken in the event of an emergency

asdf

23. State the measures to be implemented to ensure the safe handling of medicines and to promote and control conipliances with the prescribed instructions

24. Evaluation of results, state the description of methodology (e.g. statistical methods)

asfd

25. State how the persons or owners of animals are to be informed about the trial

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26. State how the staff involved are to be informed about the way the trial is to be conducted and about the procedures for medicine itsat.,,e and administration and what to do in an emergency

z

27. State whether there are any ethical or moral considerations relating to the trial, giving details

x

28. State the name and address of the company who will insure all the participants in the proposed trial

x

Insurance letter and policy

29. State the amount of insurance in respect of each participant

30. State the quantity of the medicine for which exemption is required if the mediAne is not registered

31. Particulars of persons who will take part in the clinical trial

Name	Occupation	Address	Date & place of Birth

32. Particulars of the animals that will take part in the clinical Trial Kind and breed of animal Age of animal if known Names and Addresses of owners of animals

s

33. Attached is a sample of the medicine, together with methods of analysis and storage conditions.

Date

Signature of applicant