DRUG

NATIONAL AUTHORITY

CONDUCT OF ECTOPARASITICIDE TRIALS

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Conduct of Ectoparasiticide Trials

Doc. No.: DID/GDL/002 Revision Date: 28th Feb 2013 Review Due Date: 12th March 2016

Revision No.: 0 Effective Date : 12th March 2013

Authorization of these guidelines

	Authorized by
Title	Executive Secretary/Registrar
Name	Gordon K. Sematiko
Signature	
Date	28th February 2013

Conduct of Ectoparasiticide Trials

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PART I – PRELIMINARY

1. Interpretation

In these Regulations, unless the context otherwise requires:

"Act" means the National Drug Policy and Authority Act;

"Authority" means the National Drug Authority;

"adverse drug reaction" means the unwanted, negative consequences associated with the use of given ectoparasiticide at normal doses;

"adverse event" means any untoward change in health or "side-effect" that occurs in an animal used in a trial while receiving the treatment (trial ectoparasiticide, application device, etc.) or within a pre-specified period of time after the treatment has been completed;

"applicant" means a Contracted Research Organization (CRO) with a permanent address in Uganda and reorganized by law.

"ectoparasiticide" refers to an agent that is applied directly to the host to kill ectoparasites i.e. ticks, mites, lice, fleas, tsetse flies, biting and nuisance flies;

"efficacy" means the extent to which a drug works under ideal circumstances i.e. in trials and a laboratory study;

"trial" means ectoparasiticide trial in Uganda;

"trail product" means ectoparasiticide

"trial protocol" refers to a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial;

"guideline" means a document that aims to streamline particular processes according to a set routine;
"licence" refers to a trial licence issued by the Authority under section 40 of the National Drug Policy and Authority;

"principal investigator" refers to an individual who is qualified by training and has experience as an appropriate expert who conducts a research study, and where appropriate, under whose immediate direction the investigational agent is administered or dispensed;

"sponsor" means an individual or entity interested in registering or keeping on register an ectoparasiticide, and therefore is responsible for provision of the trial product, the information pertaining that trial product and funds the trial.

2. Objectives

2.1 The objectives of these guidelines are:

1) to give guidance on the nature and extent of the efficacy data required to gain commercial or pre-registration approval of ectoparasiticides in Uganda.

2) to set out the procedures for conducting ectoparasiticide trials in Uganda and the steps that the Authority will take to review, evaluate and permit the conduct of such trials;

3) to set minimum requirements for conducting ectoparasiticide trials;

4) to establish the efficacy and safety of products used on animals against ectoparasites of veterinary importance; and

5) to ascertain that the ectoparasiticide is safe for the environment and the people exposed to the products

3. Scope

This guideline refers to the conduct of ectoparasiticide trials in Uganda.

4. Policy

The guideline is made under Section 35 (1)a and b, Section 40 and section 64 of the National Drug Policy and Authority, Act Cap 206.

5. Distribution

1) Executive Secretary / Registrar, NDA
2) Contracted Research Organizations
3) Sponsors of trials
4) NDA website
5) A shared folder for all staff on NDA head office server (\\ndaserver\qms\guidelines)
6) A shared folder for all staff on NDA laboratory server (\\ndqsvr\qms\guidelines)

PART II IMPORTATION AND MANUFACTURE OF ECTOPARASITICIDE TRIAL PRODUCT

6. Pre registration requirement to Import or Manufacture ectoparasiticides

6.1 All un registered ectoparasiticides shall require to be tested under Uganda`s field conditions to ascertain their effectiveness and safety in the indicated animals species, safety of the human beings and the environment that shall be exposed to these ectoparasiticides before they are registered in Uganda.

6.2 Laboratory experiments shall also be carried out on the trial products to ascertain both their quality and efficacy.

6.3 All trials shall be conducted using the final formulation intended for marketing in Uganda.

7. Trial of ectoparasiticides on the market

7.1 Ectoparasiticides registered for use in Uganda shall be retested under field conditions for efficacy and safety if/when the Authority and/or the Commissioner responsible for Animal Health and Entomology of the then Ministry of Agriculture Animal Industry and Fisheries so advises.

8. Application to import trial products

8.1 An application to import trail products shall be made by the sponsor himself or by an authorized company with a permanent address in Uganda.

9. Issuance of an import / manufacturing permit for trial products

9.1 Prior to importation or manufacture of an ectoparasiticide trial product, the sponsor shall apply for an import /manufacturing permit from the Authority.

9.2 The issuance of a permit to import or manufacture a trial- related product shall depend on the approval of the trial.

9.3 A product including a placebo, which is not registered with the Authority and is to be imported for the purpose of a trial shall have an import permit.

9.4 A product with a marketing authorization (registered product) when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication or when used to gain further information about an approved use in a trial also requires a trial permit.

10. Importation and release of ectoparasiticide trial products

10.1 The shipping of an investigational product shall be conducted according to instructions given by or on behalf of the Sponsor in the shipping order.

10.2 A pre-clearance inspection shall be carried out at the port of entry by the Authority.

10.3 The pre-clearance inspection shall include the shipping documentation and overall physical condition of the consignment as in ***schedule 5*** of this guideline.

10.4 If specific storage conditions are essential to ensure the quality of the product, a device that will confirm that storage temperatures are not exceeded during transport shall be included with the shipment.

10.5 Any person who supplies false or misleading information in connection with his/ her application for a trial product import permit commits an offence under ***section 60*** of the National Drug Policy and Authority Act.

11. Documentation for ectoparasiticide trail product release

11.1 The Authority Inspector at the port of entry shall base on the documentation accompanying the consignment of ectoparasiticide trial product to release the product to the sponsor as in *checklist 2* of this guideline.

11.2 The *checklist 2* shall be completed by the Sponsor and it shall accompany each consignment of trial product.

11.3 The inspector at the port of entry shall cross *checklist 2* filled in by the sponsor to ensure that the required document are attached and correct.

11.4 The documentation shall include:

1) a copy of the letter of approval of trial; and

2) the Certificate of Analysis of each batch of the investigational product as well as the comparator where applicable;

3) a copy of a valid Certificate of Manufacture issued by the competent regulatory Authority in the country of origin of the trial product.

PART III SUBMISSION OF APPLICATION TO CONDUCT ECTOPARASITICIDE TRIALS

12. Application to conduct ectoparasiticide trials

12.1 A Contracted Research Organization with a permanent address in Uganda and reorganized by law shall apply to the Authority to conduct trials.

12.2 The Application shall indicate the name, physical address, telephone number, fax number, and e – mail address of the Contracted Research Organization.

12.3 The application for authorization to conduct a trial shall be made in the format and numbering set out in the trial application form specified in the Schedule 1of these guidelines.

12.4 The text and diagrams in the application must be clear and legible.

12.5 Each section in the trial application form shall be cross-referenced to the detail in the trial protocol, investigators brochure, and other appended documents.

12.6 Only one copy of completed form shall be submitted for each application.

12.7 An application for authorization to conduct a trial shall be accompanied with a non-refundable application fee.

12.8 The Authority shall from time to time determine the trial application fee.

13. Presentation of application

13.1 The application shall be bound in a single volume or series of volumes and the pages numbered sequentially.

13.2 The appended documents shall be bound together with the application, with tabbed sections identifying each appended document.

14. Supporting documents

14.1 The applicant shall attach complete, legible copies of key peer reviewed publications, protocols of studies carried out elsewhere supporting the information in the application.

14.2 The supporting documents shall be cross-referenced from within the trial application.

15. Electronic format

15.1 The protocol, investigators brochure, and reference publications shall be supplied on appropriate data storage device.

16. Language

16.1 An application for a trial licence, other data, particulars, supporting documents, labels and package inserts shall be in English.

16.2 Where supporting documents are not in English, a copy of the document in its original language shall be accompanied by an authenticated translation in English.

17. Confidentiality

17.1 The Authority shall maintain the confidentiality of any information submitted as part of a trial application, supporting documents or associated correspondence.

17.2 The Authority may enter into a separate, trial-specific, confidentiality agreement with the applicant prior to an application, if the applicant requests.

PART IV - EVALUATION OF APPLICATION

18. Completeness of application

18.1 The Authority shall vet the application for completeness as in ***checklist 1*** of this guideline.

18.2 The application shall be deemed complete if it includes; the filled in trial application form as ***in schedule 1***, the Contracted Research Organization administrative information as in ***schedule 2***, the protocol as ***in schedule 3,*** a complete ***checklist 1*** of this guideline, proof of payment of trial fees (by attaching the NDA yellow pay slip) all necessary documentations (appendices, attachments, and any other information that may be demanded by the Authority).

18.3 Data from trials conducted from other countries on the same product shall be submitted to support the application.

18.4 The data shall represent nationally and internationally acceptable standards.

19. Application reference number

19.1 The Authority shall issue an acknowledgement of receipt of a complete application with a reference number for each application received.

19.2 The reference number shall be quoted in all correspondence concerning the application.

20. Supplementary information and update

20.1 Any new information available on the product such as adverse effects, change of manufacturer shall be reported in writing to the Authority.

20.2 The Contracted Research Organization shall immediately inform the Authority of any changes that may affect the conduct and outcome of the trial.

20.3 The Contracted Research Organization and the Authority shall inform either party about circumstances that may lead to the amendment of the trial application when necessary and the sponsor too shall be informed of the decision.

20.4 The Authority shall request for further supplementary data or documentation when appropriate.

20.5 Supplementary information shall be given to the Authority in case of additional quantity of trial product(s), additional trial site(s), change in trial sites, additional manufacturing site or re-packer, change of port of entry, and change of Contracted Research Organization, extension of product's shelf life accordingly, according to the respective roles as stipulated in *section 19* and *20* of this guideline.

21. Expert review

21.1 When circumstances warrant, the application shall be reviewed by relevant committees of the Authority with experts drawn from among others Ministry of Agriculture Animal Industry and Fisheries (MAAIF), Uganda National Council of Science and Technology (UNCST), Research Institutions, Academic Institutions, Uganda Veterinary Association (UVA), and National Environment Management Authority (NEMA).

21.2 There shall be a confidentiality agreement with the reviewers to ensure that the contents of the application remain confidential.

21.3 The reviewers shall not have direct contact with the applicant and all correspondences shall be directed to the Authority.

21.4 The report and recommendations of the reviewers shall be considered by the Authority.

22. Final decision

22.1 The Authority reserves the right to approve or ask for amendment or reject the trial application.

22.2 The Authority shall communicate the decision made to the applicant in writing and in case of rejection give reasons.

22.3 The applicant may appeal the decision of the Authority.

PART V - RESPONSIBILITIES OF THE STAKEHOLDERS IN CONDUCT OF ECTOPARASITICIDE TRIALS.

23. Responsibilities of the sponsor

23.1 The sponsor shall perform the following duties:

1) supply the investigational product to the identified Contracted Research Organization for the purposes and use stated in the trial application;

2) be responsible for the product and the information supplied in support of his or her application for a trial authorisation as is in ***schedule 7*** of this guideline;

3) be responsible for updating any information relevant to the product or application;

4) In cases where the sponsor is not the manufacturer and where secrecy considerations prevent disclosure of certain information to the Contracted Research Organization, such information may be furnished to Authority through the applicant in a sealed envelope marked CONFIDENTIAL .

5) not supply the trail product until all the required authorization has been obtained by the Authority.

6) ensure that the trial product (including active comparator(s) and placebo, if applicable) is characterized as appropriate to the stage of development of the product, is manufactured in accordance with any applicable good manufacturing practice and is coded and labeled in a manner that protects blinding, if applicable.

7) state the investigational product, acceptable storage conditions such as temperature, protection from light, shelf life, indications and contra indications, reconstitution fluids and procedures, and devices for product application.

8) ensure timely delivery of a trial product to the Contracted Research Organization.

9) maintain records and documents of shipment, receipt, disposition, return and destruction of the trial product,

10) maintain a system for retrieving trial products and documenting this retrieval such as for deficient product recall, reclaim after trial completion, expired product reclaim,

11) dispose unused trial product and document the process in compliance with national standards for the disposal of pharmaceutical waste,

12) provide sufficient quantities of the trail product used in the trial to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics.

13) retain samples either until the analysis of the trial data is complete or as required by the Authority to the extent stability permits whichever represents the longer retention period.

14) submit a letter of agreement to the Authority from the recommended Contracted Research Organization for the conduct of a trial;

24. Responsibilities of the Contracted Research Organization

24.1 The Contracted Research Organization shall perform the following duties:

1) with reference to information provided by the sponsor shall develop a protocol for conducting ectoparasiticide trial which shall be submitted to the Authority for approval;

2) confirm in writing that he/she shall work according to the protocol by signing a declaration form in ***schedule 4*** of this guideline;

3) obtain informed consent from the owners of trial animals. The animal owner shall receive written information from the principal investigator/Contracted Research Organization in advance;

4) provide all relevant information to the support staff and all scientists including the area veterinarian involved in the trial;

5) ensure that the investigational product(s) are correctly stored to prevent theft or illegal distribution, safely handled and dispensed to trial animals in accordance with the protocol;

6) maintain a full inventory of receipt, usage and remaining stocks so that at the end of the trial it is possible to reconcile delivery records with those of usage and returns including accounting for any discrepancies;

7) observe all procedures and documentation with due professional care in accordance with the protocol;

8) justify, notify and seek consent from the sponsor and the Authority the need for amendment to the protocol;

9) report any suspected adverse event(s) to the Authority within 48 hours;

10) make all data available to the Authority for the purposes of validation;

11) forward signed Record Sheets to the Authority. Collaborative Investigators and those responsible for the analyses (including statistical analyses) and the interpretation of the results shall also sign the relevant Record Sheets. Where appropriate, all practice records shall be clearly marked that the animal(s)/owner is participating in a clinical trial;

12) observe the following points related to animal welfare:

    i) give assurance that he/she has sufficient time to devote to the care and welfare of the trial animals,

    ii) be responsible for animals under his/her care for the purpose of the trial and ensure that their care is maintained throughout the trial.

    iii) shall ensure that the trial product is applied only to animals involved in the said trial.

PART VI - MONITORING OF ECTOPARASITICIDE TRIALS BY THE AUTHORITY

25. Inspection of trial sites

25.1 The Authority shall conduct inspection/ audit of trial sites.

25.2 The audit shall include but not be limited to compliance with the approved protocol and Good Clinical practice.

25.3 The inspections shall take place at the discretion of the Authority including but not limited to:

1) before commencement of the trial

2) at predetermined intervals

26. Reports of suspected adverse events

26.1 The investigating institution shall report to the Authority all suspected adverse events in writing within 48 hours.

26.2 The Authority shall inform the sponsor in writing about the suspected adverse drug events after causality assessment.

26.3 Additional follow up information on the suspected adverse drug events shall be made available to the Authority as soon as possible, but in any case not later than fifteen calendar days.

27. Progress and final trial reports

27.1 There shall be 3-monthly progress and/or a final report as in ***schedule 6*** of this guideline.

27.2 The contacted Research Organization shall submit the final report within 3 months from the date of completion of the trial.

27.3 The progress report shall include:

1) the number of animals and frequency of treatment;
2) the number and type of suspected adverse events reported;
3) the number of discontinued animals and the reason for discontinuation; and
4) the quantity of investigational product used.

28. Accountability and disposal of the investigational product

28.1 An accountability and disposal report of the investigational product shall be submitted to the Authority within 3 months from completion of the trial.

28.2 The report shall also include:

1) date the trial started and ended;
2) trial license number;
3) trial certificate for the relevant site;
4) date and quantity received for each investigational product;
5) balance of the investigational product;
6) product destruction certificate, and or written evidence of re-export of the unused product supplies to the country of origin (whichever is applicable).

29. Post trial review

29.1 The interim and final report from the trial shall be submitted to the Authority for consideration.

29.2 The format of the report shall be as provided in the protocol used in the trial.

30. Archiving

30.1 The Authority, the Contracted Research Organization and the Sponsor shall archive and ensure the safety of all the documents related to the trial.

30.2 The Contracted Research Organization and the Sponsor shall inform the Authority in writing prior to destroying the documents.

30.3 Documents shall be retained for as long as the product is on market.

PART VII - CONTIDITIONS FOR APPLICATION FOR A TRIAL LICENSE

31. Notification of change of information to Authority

31.1 The trial license holder shall inform the Authority of any change in information, or any information received by him or her that casts doubt on the continued validity of the data, which was submitted with, or in connection with the application for the Trial License.

32. Discontinuation of the trial

32.1 The trial license holder shall inform the Authority of any decision to discontinue the trial to which the license relates and shall state the reason for the decision.

32.2 Where a trial is discontinued, the trial license holder shall return the trial license to the Authority as soon as possible.

SCHEDULES

1. The Ectoparasiticide Trial Application Format (EFTA)

EFTA Section 1. Identification of the Trial

1.1 Title of the study
1.2 Contact person and contact details
1.3[Space for NDA Reference Number]
1.4 Declaration of intent signed by the Contracted Research Organisation

We, the undersigned have submitted all the required documentation and have disclosed all the information required for approval of this application. We have developed the Protocol and read the Investigators brochure, appended. We agree to ensure that the trial will be conducted according to the Protocol and all legal, ethical and regulatory requirements in Uganda. Applicant (Local Contact): Name date: Signature: Designation Principal Investigator: Name date: Signature: Designation

EFTA Section 2. Basic Administrative Data on the Application

Name and address of the registered office of the Applicant

Particulars	Sponsor	Manufacturer	Applicant
Name			
Physical address			
Postal address			
Telephone number			
Email			
Fax			

EFTA Section 3. Product to be used in the Trial

3.1 Investigational product

3.1.1 Identifier or name of investigational product (code if applicable)
3.1.2 Registration number (if product is already on the market)
3.1.3 Manufacturer (Include all sites)
3.1.4 Active ingredient, complete composition, potency and presentation
3.1.5 Evidence of manufacture under conditions compliant with current codes of good manufacturing practice
3.1.6 Release specifications and tests. Include Certificate of Analysis.
3.1.7 Current approved package insert if available.

3.2 Comparator, concomitant and rescue medications (antidotes) and Placebo
3.2.1 Proprietary name and INN
3.2.2 Active ingredient, composition, and presentation
3.2.3 Registration number (country)
3.2.4 Approved package insert to be appended to application.
3.2.5 Evidence that placebo is manufactured under good manufacturing practice.

3.3 Details of handling trial product.
3.3.1 Shipping, delivery and distribution of trial product.
3.3.2 Details of storage requirements and arrangements where necessary and monitoring during distribution.
3.3.3 Details of dispensing trial products and waste disposal procedures.
3.3.4 Packaging and labeling of the trial products

3.4 Estimates of quantities of each product to be used for the trial, and for which an import permit is needed.

EFTA Section 4. History of previous and in-progress trials

4.1 List the titles of previous trials with this (or similar) trial product in Uganda or in other countries.

4.2 Include a letter or certificate from the regulatory authorities in countries where previous trials have been undertaken (including those in-progress) that these trials have been GCP compliant.

4.3 Append interim or final report-summaries of these trials to this application. (This may be in the investigators brochure

2. The Contracted Research Organisation Administrative Information

2.1

Name	
Physical address	
Contact person (Director)	
Declaration of capacity & interests	

2.2 For each site list the following:

2.2.1 Site Identifier (Name)
Physical address: (include GPS coordinates)
Telephone & fax numbers
E-mail address

2.2.2 Description of the site facility & staff
(a) Infrastructure on the farm;
(b) Facility for special examination (if required);
(c) Capacity to collect, prepare, store and transport field samples;
(d) Storage and handling facility for the trial product; and
(e) Name and qualification of person with responsibility for dispensing trial product.

3.1 Site Principal Investigator

Name	
Qualifications	
Contact details	
Physical address	
Declaration of capacity & interests	

3.2 Site Sub-investigator and trial-specific support staff

Name:	
Qualifications	
Contact details	
Physical address	
Declaration of capacity & interests	

3.3 For animal farm Sites

(a) Responsible administrator or farmer;
(b) Contact details; and

(c)Append signed letter of agreement for trial to take place.

3.4 Append signed agreement between the Investigating institution and the Sponsor or field research organization. (Appendix 13)

4.1 Trial Animals

4.1.1 Number of animals as stipulated in the table below

Number of trial sites	
Total number of animals to be enrolled in all sites	
Intended number of animals at each site – evidence of availability	

4.1.2 Duration

4.1.3 Estimated trial duration: Date initiated to end

6.3 The intended compensation in case of loss or injury to the animals in the trial shall be un understanding between the applicant and the investigating institution.

NB. This will be after confirmation that the loss or injury of was due to the trial product.

5.1 Trial monitoring and reports

5.1.1 Describe the safety and monitoring plan for each site.

5.1.2 Describe the system to be used to detect, record, assign causality and the actions for adverse events.

5.1.3 Describe the actions to be taken following reports of suspected adverse events.

5.1.4 When will interim reports be submitted?

5.1.5 Final report - estimated due-date?

6.1 Insurance

6.1.1 Provide a copy of the current insurance certificate.

6.1.2 Provide evidence that each member of the investigating team is covered by relevant malpractice insurance for this trial

7.1 Description of the Trial

7.1.1 Is the title of the trial fully descriptive?

7.1.2 Summarized rationale for this trial, including relevance to Uganda

7.1.3 Brief background information shall include:

(a) The problem statement and the justification of the trial;
(b) Properties of the trial product- hypothesis for action
(c) Description of risks of the protocol and the potential harms of the trial product.
(d) summary report that establishes probable safety and efficacy of the investigational product in animals.

(e) Include evidence that the formulations used in the pre-field and previous trials are identical to that in this application. Any variations should be highlighted and justified. *

(f) Published reviews or reports relevant to the indicated ectoparasites and this type of product

8.0 Objectives of this trial (List as primary and secondary objectives and provide justification)

8.1 Trial design: describe and justify each component;

8.2 The eligibility of the animals involved in the trial in relation to:

(a) Inclusion criteria - list and justify each

(b) Exclusion criteria - list and justify each

9.5.2 The treatment regimens for each group.

9.5.3 Follow-up, sampling collection and monitoring plans; immediate monitoring - intermediate monitoring - long term monitoring.

9.6 Outcomes measurements and analysis

9.6.1 Describe each outcome or variable (including safety and efficacy)

9.6.2 Describe the samples that will be collected and the analyses to be conducted on each sample

9.6.3 Provide evidence that the laboratories that will conduct the safety screening, and the end-point assays are accredited and competent to do the assays. (where applicable)

9.6.4 Describe the intended statistical analysis to be conducted. Provide evidence that the study is powered to provide the intended outcome.

9.7 Are any sub-studies intended? Provide full details.

9.8 Will field samples be stored for any period beyond the duration of this trial?

9.8.1 What is the purpose of such archiving?

9.8.2 What controls are to be placed on their confidentiality and possible future use?

9.9 Informed consent from animal owners.

9.9.1 Append a copy of informed consent from animal owners.

9.9.2 Are there separate informed consent from animal owners for sub-studies.

10. Publication policy

Provide details of the investigators and Sponsors intentions and freedom to publish the outcomes of this trial

3. Format for the Ectoparasiticide Trial Protocol

When designing a study protocol, the mode of action exhibited by the active substance e.g. killing, repellent, anti-feeding, as well as the life cycle of the parasite e.g. length, seasonality; parasitic stages shall be taken into account,

N.B: The protocol shall contain the following particulars, where applicable:

1. Name and particulars of the product

(a) State the name or code number under which the product will be imported and known during the trial. A separate application is required for each trial

(b) State clearly the proprietary name, approved or INN or generic name, strength or dosage form, pharmaceutical form, description, labeling, include also information leaflet of the product.

2. Details of the manufacturer

(a) Name of the manufacturer

(b) Physical address

(c) Postal address, telephone, Fax, email and website

(d) Country of origin

3. Identification of the trial

(a) Title of the trial
(b) Version

Aim of the Trial

a) State the objective(s)
b) Rationale of trial.

5. Trial sites

At least two sites in two different geographical zones shall be considered.

6. Tentative trial dates

NB: The trial shall be conducted for a continuous period of six months to cater for the wet and dry seasons in Uganda.
(a) Trial initiation
(b) Trial completion

7. Investigating institution

(a) Name of the investigating institution
(b) Name of the investigator
(c) Curriculum Vitae and attached testimonials
(d) Address
(e) Telephone number(s)
(f) Email(s)/Fax

8. Sponsor

(a) Name
(b) Address
(c) Telephone numbers, email, Fax

9. Trial animals

(a) Species
(b) Identification number of animal
(c) Number of animals involved in the trial
(d) Sex
(e) Age
(f) Weight

10. Husbandry
Complete description of management systems

11. Description of the trial
Animals shall be infested with suitable numbers of parasites. The adequacy of infestation shall be addressed in the statistical, parasitological and clinical relevance of the level of infestation. Untreated control groups shall be used provided there are no serious welfare implications of the disease.

a) Trial design (e.g. randomized controlled trial, open- label parallel group, cross-over technique)
b) Criteria for inclusion of potential trial animals and exclusion of some
c) Group allocation

d) Treatment procedure including other treatments these animals will receive during the study irrespective whether there is interaction with the product under investigation.
e) Sample size: Statistically adequate numbers of treated and control animals should be included in each trial in order to achieve the trial objective(s) based on statistical consideration (sufficient to allow dropout, variability of effect etc).
f) The applicant is required to justify the group size and it is recommended to seek the advice of a statistician.
g) Ectoparasite count according to stages of engorgement and species shall be indicated.

NB. An appropriate method shall be described to fit this purpose.

12. Demonstration of efficacy

(a) Methods used for the assessment of efficacy shall be relevant for the parasite species involved and for the level of efficacy to be demonstrated.

(b) Methods used for the assessment of efficacy shall be justified

13. Efficacy calculations

A description of the method used to calculate efficacy of the product shall be provided.

14. Test facilities, equipment, and materials

There shall be-

(a) in case of large animals, adequate pasture for continued exposure to re-infestation;
(b) suitable handling facilities for handling the animals during ectoparasiticide counts;
(c) suitable equipment and measuring containers for accurate measurements and application of the trial formulation as well as that of the positive control formulation; and
(d) protective clothing, appropriate to the type of formulation under test.

15. **Suspected adverse event**

There shall be in place -

(a) methods of recording and reporting suspected adverse events or reactions; and
(b) provisions for dealing with complications for example anti dots.

16. Evaluation of results

(a) A description of data management procedures shall be provided.
(b) Statistical methods and considerations. Any statistical significant difference between the treated and the control group shall always be interpreted in terms of biological and clinical significance.
(c) Participants withdrawn from the trial shall be indicated and the reasons for withdrawal shall be indicated.

17. Compensation of owner

A statement about compensation of animal owner shall be included in case of death and injury of trial animals as a result of the trial.

18. Environment Impact Assessment (EIA)

Proof of an Environment Impact Assessment study shall be submitted at the end of the study.

4. Format for Declaration by the Investigators

Trial protocol number. . . . . .
Name: ……..
Role in trial ……..
Trial title: ……..
Site: A current Curriculum Vitae is attached.

I am aware of the responsibilities of my role as . . . . . in trial number . . . . . as required by the legal, ethical and regulatory requirements of Uganda.

I have read and understand the attached Protocol, investigators brochure and supporting documentation and I will comply with the procedures and requirements included in them.

I have read the attached trial application form as submitted to the National Drug Authority in Uganda and confirm that the information is complete, true and accurate, and conform to the protocol and supporting documentation.

I will not commence with this trial before written authorization has been received from the Uganda National Drug Authority and other government bodies as may be required. I will provide the NDA and other relevant bodies with reports as required.

I will obtain Informed consent from all animal owners participating in the trial. I will ensure that every animal in the trial will be treated ethically.

I will ensure that the District Veterinary Officer and the area veterinarian are aware and involved in the trial.

I DECLARE: I have no conflict of interest in terms of financial interests or personal relationships that may inappropriately influence my responsibilities and conduct of this trial.
Initials: . . . . . .

I DECLARE: I have not previously been associated with any trial that has been terminated, or study-site that was closed, due to failure to comply with Good Clinical Practice for the conduct of trials on veterinary medicinal products..
Initials:…….

SIGNED ……..DATE ……

WITNESS:……NAME ……..DATE …….

SCHEDULE **: Letter of Authorization from Manufacturer**

Date: ……
(Company's Name) ……..

A company operating under the laws of ……., located in ……,
Local company name and address

Tel No: ……
Fax No:……
E-mail: ……..

To represent us in Uganda for the application of the Trial Licence for:
Protocol No : ……
Release date: ……

……..……..(The local company's name and address) is authorized to be the Trial Licence Holder and will be responsible for all matters pertaining to the Trial Licence application for the above mentioned trial protocol.
Yours faithfully.

……
Authorized name & signature

5. Format for Labelling Trial Products

Outer/carton labels & Unit Pack

The following information shall be presented on the labeling of the product for trial:

Parameters	*Outer/carton labels*	*Unit Pack*
Study No. or Protocol	?	?
Group code	?	?
Product name or code	?	?
Dosage form	?**	?**
Name of active substance	?**	?**
Strength of active substance	?**	?**
Dilution for different species	?	?
Batch number	?**	?**
Manufacturing date or retes date	?	?
Expiry date	?	?
For Trial Use Only	?	?
Name and address o manufacturer or final releas or product owner (corporat address)or sponsor	?***	?***
Route of administration	?	?
Storage conditions	?	?
Pack sizes (unit/Vol)	?	?

** Where applicable

*** With letter of authorization

If the product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner carton.

6. Format for Study Reports

1. Title page
2. Synopsis
3. Table of contents for the individual study report
4. List of abbreviations and definition of terms
5. Ethics
6. Investigating institution / investigator and study administrative structure
7. Introduction
8. Study objectives
9. Investigation plans
1 0. Trial animals
11. Efficacy evaluation
12. Safety evaluation
13. Discussion and overall conclusion
14. Tables, figures and graphs referred to but not included in the text
15. Reference list
16. Appendices

Sample Interim or End of Study Summary Report

Date
The Executive Secretary
National Drug Authority
Attention: Head, Drug Information Department
Dear < Insert Name>
INTERIM OR END OF STUDY SUMMARY REPORT <Whichever applicable>
< Trial Protocol Title and Protocol Number>
<NDA reference number>
The following is a summary of the <study title> trial conducted in <insert institution name>:
Number of animals screened: < insert number**>**
Number of animals randomized: **<**insert number**>**
Number of animals discontinued: **<** insert number**>**
Reasons for discontinued: **<**insert number>
Reason for discontinuation: **<**List of individual discontinued animals
Number of animals completed study: **<** insert number**>**
Number of Suspected adverse events: **<** insert number**>**
Number of endpoints: <insert number if applicable, if not, to be removed>
Last batch of drug supplies collected back from site: < insert date>
Last batch of drug supplies sent back to < originating site> for destruction: <insert date>; if local destruction, attach copy of NDA destruction certificate.
List of any changes in trial personnel – including full Curriculum Vitae and declaration
List of monitor and audit reports to date.

7. Information to be given to the Contracted Research Organisation to aid them in developing the Trial Protocol

1. Finished Product

(a) Description (physical characteristics):
(b) 1.2 Composition (Complete Formula)
(c) Active Ingredient

Active Ingredient(s):	
Content	

(d) Other Ingredients (adjuncts, excipents, preservative, colour, smell, etc):

Name of Other Ingredient(s)	
Content	

(e)Packing or pack size (brief)

2. Manufacture of Product

(a) Complete batch manufacturing master formula

Name of Ingredients (active an otherwise)	
Quantities used per batch	

(b) Manufacturing process:
(c) Brief description and principles.

3. Quality Control

(a) State whether quality control is done in part or solely by the manufacturer's own quality control department or an external laboratory.
(b) If quality control tests are done by an external laboratory, state:
  (i) name and address of the laboratory (where applicable);
  (ii) tests done by the external laboratory (where applicable);
  (iii) reasons why the tests are not done by the manufacturer.
(c) Specifications for ingredients, active and otherwise

Name of ingredient	
Specifications	
Source (state manufacturer or packaging etc).	

(d) Manufacturer and country of origin

3.4 In- Process quality control:

Tests performed during manufacturing process and sampling protocols:

Tests	
Stage at which tests done	
Frequency of sampling	
Quality of sample taken each time	

3.5 Finished product quality control:

Tests and specification limits (check and release specifications)

Test	
Acceptance limits	
Release for test method and limits (manufacturers, etc)	

The Certificate of Analysis to be certified by Quality Assurance Manager.
Certificate of Analysis of recent batch of product **(minimum 1 batch)** enclosed:

4. Stability of Product:

4.1 Storage condition must be included on the label.

4.2 Proposed shelf life of product:

N.B In the event that the extension of shelf life for trial material is required, industry will provide supportive data to support the extension.

CHECKLISTS

1. Required Documents at submitting in Application

Item	Requirement
Fees	Proof of payment
Materials transfer:	Applications for import and/or export of materials
FTA	Trial Application Form
Protocol	Complete and elaborate document
APPENDIX 1:	Investigators Brochure
APPENDIX 2:	Animal owner information leaflet and Informed Consent Form
APPENDIX 3:	Certificate of Good Manufacturing Practice manufacture of the trial product or other evidence of manufacture quality, safety and consistency
APPENDIX 4:	Package insert/s for other trial products.
APPENDIX 5:	Certificate of Good Manufacturing Practice manufacture of the placebo – where applicable.
APPENDIX 6:	Evidence of accreditation of the designated laboratories or other evidence of GLP and assay validation.
APPENDIX 7:	Insurance Certificate specific for the trial in consultation with NDA.
APPENDIX 8:	Signed and completed Declarations by all Investigators.
APPENDIX 9:	Full, legible copies of key, peer-reviewed published articles supporting the application.
APPENDIX 10:	Sample of the label for the trial products
APPENDIX 12:	Letter of authorization from the manufacturer/product owner
APPENDIX 13:	Pharmaceutical Data on dosage form and any other relevant information
APPENDIX 14:	Other supporting documents.

2. Required Documents by the Authority Inspector at the Port of Entry

To be supplied by the sponsor for use by the Authority Inspector at the port of entry to authorize the importation of the trial product.

Importation and Release of Investigational Products			
Checklist of required documentation			
Are the following documents attached and correct, as indicated?		**YES**	**NO**
1	A copy of NDA letter of approval of trial		
3	CoA reflect at least the following information:		
	Product name or code		
	Name of company / Sponsor		
	Batch number		
	Expiry date		
	Date of issue		
	Signature, qualification and title of responsible person		
	Results of physical and analytical tests		
4	A copy of valid Certificate of Manufacture issued by the competer Regulatory Authority in the country of origin		
5	Application device included (if applicable)		
6	The label clearly indicate Labeling: *outer packaging, immediate container*		
6.1	The product is trial material, e.g. “For use in trial only”		
6.2	Product name or unique code (if blinded)		
6.3	The Storage temperature is stated		
6.4	The Storage conditions indicated (e.g. protection from light)		
6.5	The Batch number is stated		
6.6	The Date of manufacture is stated		
6.7	The Expiry date is stated		
6.8	Details of Sponsor`s contacts is included		
7.0	The physical condition of the consignment is acceptable		

Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
15th/02/2013	0	DID/GDL/002	1. Dr. Muhindo Jeanne Bukeka 2. Mrs. Helen Byomire Ndagije	This is the first issue of this document

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