

**GUIDELINES FOR CONDUCTING VETERINARY PESTICIDES FIELD TRIALS (SAFETY AND EFFICACY) AND RELEVANT TEMPLATE(S)**

|  |  |
| --- | --- |
| Draft agreed by Technical Working Group |  |
| Draft released for consultation by representatives of East African region regulatory agencies |  |
| End of consultation period |  |
| EAC code | PSS/1/1/21/…….. |
| Enters into force |  |

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# **Acronyms**

OECD: Organization for Economic Co-operation and Development

# **Definition**

1. Interpretation

In these guidelines, unless the context otherwise requires:

“Act” means the acpplicable National laws in the EAC Partner State;

“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 sponsor or Contracted Research Organization (CRO) or authorized company with a permanent address in Uganda and reorganized by law.

“Competent Authority” means the competent agency/institution responsible for pesticides registration;

“veterinary pesticide” / “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 pesticide works under ideal circumstances i.e. in trials and a laboratory study;

“field trial” means an ectoparasiticide field trial;

“guideline” means a document that aims to streamline particular processes according to a set routine;

“Informed Consent” A process by which a study participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the study participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

“Inspection” The act of conducting an official review of documents, facilities, records, and any other resources that are deemed by the Authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or CRO‟s facilities or at other establishments deemed appropriate by the Authority.

“Investigator” A physician, dentist or other qualified person who conducts a clinical trial at a trial site. See also Sub-investigator

“licence” refers to a trial licence issued by the competent Authority under laws of the country where the trials is to be conducted;

“Multi-centre Trial” A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

“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;

“Protocol” A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The protocol usually also gives the background and rationale for the trial but these could be provided in other protocol referenced documents;

“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.

“trial product” means ectoparasiticide

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

“trial” means ectoparasiticide trial;

“Trial Site” The location(s) where trial-related activities are actually conducted.

1. **Introduction**

This guideline gives guidance on how to conduct the efficacy trials of products in cattle against all arthropod species that need animal involvement for completing their life cycle, i.e. where at least one parasitic stage occurs in/on the animal or feeds on the animal. Guidance is aimed at the principal ectoparasites found in cattle (mites, lice and ticks) but could be adapted to study the efficacy of products against less common (regional) ectoparasites and arthropod-related disorders, providing that any adjustments to the methods are justified. The scope of this guideline includes nuisance and biting flies because similar principles exist for the demonstration of efficacy.

This guideline describes the procedure for the conducting of efficacy studies in the EAC region under field conditions. The intention is to establish the impact of the different weather conditions (extreme heat, light intensity, stormy rain etc) on the performance of the pesticide under study.

Applications to requesting to conduct ectoparasiticide field efficacy trials studies shall be submitted to the competent authorities according to the EAC MRP participating country guidelines for the approvals in each of the EAC Partner State using the addresses below.

**Burundi:** [www.minagrie.gov.bu](http://www.minagrie.gov.bu)

Ministry of the Environment, Agriculture and Livestock

BP 161 Gitega, Burundi.

**DRC:**

**Kenya:** [www.vmd.go.ke](http://www.vmd.go.ke)

Veterinary Medicines Directorate

P. O. Box 66171-00800

NAIROBI, KENYA.

Email: vmd@kilimo.go.ke

**Rwanda:** rwandafda.gov.rw

Rwanda Food and Drugs Authority

Please provide the full address of the Authority

**South Sudan:** <http://mar.gov.sd/>.

Ministry of Livestock and Fisheries

Please provide full address of you Ministry

**United Republic of Tanzania:** <https://www.tmda.go.tz/>.

Ministry of Livestock and Fisheries

Please provide full address of you Ministry

**Uganda**: [www.nda.or.ug](http://www.nda.or.ug)

The National Council of Science and Technology-Kampala,

The Commissioner of Veterinary Services, Ministry of Agriculture, Animal Industry and Fisheries, Entebbe,

The National Drug Authority,

Plot 46-48, Lumumba Avenue

P. O. Box 32096, Kampala

*This guideline should be read together with the Laws and Regulations governing ectoparasitecides Efficacy Field trials studies in the different EAC Partner States.*

# **Objectives**

* 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 East African Community.
     2. To set out the procedures for conducting ectoparasiticide efficacy trials in the region and the steps that the national competent 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.

# **Scope**

This guideline is intended to provide guidance in respect of the documentation of the efficacy of ectoparasiticides including the environmental impact on the ectoparasitecide. All the manufacturer claims for control of infestation, the period of time it takes to achieve control and the period over which control is achieved must be demonstrated. This guideline provides the minimum requirement for ectoparasiticide efficacy trials in the East African Community Partner States. It provides guidance for the design and execution of laboratory and field studies to evaluate the performance of veterinary pesticide products applied on the animal body. Minimum data requirements for field efficacy trials of the product must be provided to support regulatory authorization in the EAC region. All studies should be conducted according to international scientifically recognized quality standard.

The guideline covers studies conducted in cattle and can be extrapolated to other related animals in the EAC region which are raised entirely under free range system.

# **Policy**

The guideline is made in accordance to treaty establishing EAC, Ch. 8, Art 108 (e)

# **IMPORTATION OF ECTOPARASITICIDE TRIAL PRODUCT**

* 1. All un-registered ectoparasiticides shall be tested under local field conditions within the EAC region to ascertain their effectiveness and safety in the indicated animal’s species, and safety to the human beings and the environment that shall be exposed to these products before they are registered for use in the region.
  2. Laboratory experiments shall also be carried out on the trial products to ascertain both their quality and efficacy.
  3. All trials shall be conducted using the final formulation intended for marketing in region.

# **Efficacy Trial of ectoparasiticides intended for registration in the region**

* 1. General requirements for efficacy trials;
     1. All trials shall be supervised and/or conducted by qualified and experienced persons;
     2. All trials shall be replicated, with a minimum of three replicates. A negative control must be included in the trial.
     3. Wherever relevant, all registration applications will be accompanied by results from at least one laboratory trial, unless stipulated otherwise and two seasons field trials for products.
     4. All efficacy data must be generated from trials conducted in East African country. Additional data from trials in other countries may be submitted as supporting data in a registration application, solely to support any label claims. Where no capacity exists in EAC region to conduct specific pest/application method trials, then the registration applicant must consult with the competent authority for pesticide registration on conducting a trial outside of EAC, or whether the specified trial/pest/application method claim can be waived for registration.
     5. Residual surface sprays are normally used for indoor applications. Where the label makes mention of exterior use, field trials are required. Since this guideline is for outdoor/field trials only, indoor applications studies have been omitted.
     6. Trials must include a standard registered (reference) product for comparison purposes. Sometimes no standard product will exist – e.g. when a new formulation type is being tested for the first time for registration. Under these circumstances it is still possible to include a standard (reference) registered product, the use of which is intended to give the same control result as that planned with the new product/formulation (e.g. 75% control of a specific pest species or application type or combination of both).
     7. Ectoparasiticides registered for use in one of East Africa countries and EAC guideline were not applied it may be retested under field conditions for efficacy and safety if/when the Authority and/or the Commissioner responsible for Veterinary Services Ministry of Livestock of the respective EAC PS so advises.

# **Application to import trial products**

* 1. An application to import trial products shall be made by the Sponsor or by an authorized company or a Contracted Research Organization with a permanent address in the EAC Partner State and according to specific regulations governing importation of samples.

# **Issuance of an import permit and a manufacturing license for trial products**

* + 1. Prior to importation or manufacture of a pesticide trial product, the sponsor shall apply for an import permit /manufacturing license (in the case of a domestically produced veterinary pesticide) from the competent registration Authority in the EAC PS.
    2. The issuance of a permit to import or a licence to manufacture a trial- related product shall depend on the approval of the trial.
    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.
    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.

# **Importation and release of pesticide trial products**

* 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.
  2. A pre-clearance inspection shall be carried out at the port of entry by the Authority.
  3. The pre-clearance inspection shall include the shipping documentation and overall physical condition of the consignment for (schedule 5) of this guideline.
  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.
  5. Any person who supplies false or misleading information in connection with his/ her application for a trial product import permit commits an offence and such defaults shall be handled under the different sections of the National Acts.

# **Documentation for pesticides trial product release**

* 1. The Authority Inspector at the port of entry shall, based on the documentation accompanying the consignment of pesticides trial product, release the product to the sponsor as in checklist 2 of this guideline.
  2. The checklist 2 shall be completed by the Sponsor and it shall accompany each consignment of trial product.
  3. The inspector at the port of entry shall crosscheck the checklist filled in by the sponsor to ensure that the required document is attached and correct.
  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.

# **SUBMISSION OF APPLICATION TO CONDUCT ECTOPARASITICIDE TRIALS**

* 1. Application to conduct ectoparasiticide/pesticide trials
  2. An accredited trial center shall be appointed based on the criteria set out on Schedule X.
  3. The Application shall indicate the name, physical address, telephone number, fax number, and e – mail address of the Contracted Research Organization.
  4. 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 form Schedule 1 of these guidelines. An application for a trial licence, other data, particulars, supporting documents, labels and package inserts shall bethe English language only. Where permitted by the authority – the administrative part of the submission may be in French.
  5. 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.
  6. The text and diagrams in the application must be clear and legible.
  7. Each section in the trial application form shall be cross-referenced to the detail in the trial protocol, investigators brochure, and other appended documents.
  8. Only one copy of completed form shall be submitted for each application.
  9. An application for authorization to conduct a trial shall be accompanied with a non-refundable application fee.
  10. The fee due for conducting the trial shall be determined by the national authority where the trial is to be conducted.
  11. **Confidentiality** 
      1. The Authority shall maintain the confidentiality of any information submitted as part of a trial application, supporting documents or associated correspondence.
      2. The Authority may enter into a separate, trial-specific, confidentiality agreement with the applicant prior to an application, if the applicant requests.

# **EVALUATION OF APPLICATION**

* 1. **Completeness of application**
  2. The Authority shall vet the application for completeness as in checklist 1 of this guideline.
  3. The application shall be deemed complete if it includes;
     1. the filled in trial Application Form (schedule 1),
     2. the Contracted Research Organization administrative information form (schedule 2),
     3. the protocol form (schedule 3),
     4. a complete checklist (checklist 1) of this guideline,
     5. proof of payment of trial fees and all necessary documentations (appendices, attachments, and any other information that may be demanded by the Authority).
  4. Data from trials conducted from other countries on the same product shall be submitted to support the application.
  5. The data shall represent nationally and internationally acceptable standards.
  6. **Application reference number** 
     1. The Authority shall issue an acknowledgement of receipt of a complete application with a reference number for each application received.
     2. The reference number shall be quoted in all correspondence concerning the application.
  7. **Supplementary information and update** 
     1. Any new information available on the product such as adverse effects, change of manufacturer shall be reported in writing to the Authority.
     2. The Contracted Research Organization shall immediately inform the Authority of any changes that may affect the conduct and outcome of the trial.
     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.
     4. The Authority shall request for further supplementary data or documentation when appropriate.
     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 9 of this guideline.
  8. **Expert review** 
     1. When circumstances warrant, the application shall be reviewed by relevant committees of the Authority with experts drawn from among others national Ministries/Authorities/Academic Institutions/Veterinary Professional Association
     2. There shall be a confidentiality agreement with the reviewers to ensure that the contents of the application remain confidential.
     3. The reviewers shall not have direct contact with the applicant and all correspondences shall be directed to the Authority.
     4. The report and recommendations of the reviewers shall be considered by the Authority.
  9. **Final decision** 
     1. The Authority reserves the right to approve or ask for amendment or reject the trial application.
     2. The Authority shall communicate the decision made to the applicant in writing and in case of rejection give reasons.
     3. The applicant may appeal the decision of the Authority.

# **- RESPONSIBILITIES OF THE STAKEHOLDERS IN CONDUCT OF ECTOPARASITICIDE TRIALS.**

* 1. **Responsibilities of the sponsor**
  2. The sponsor shall perform the following duties:
     1. supply the investigational product to the identified Accredited Center 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 form (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 trial 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 pesticide waste,
     12. provide sufficient quantities of the trial 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;
  3. **. Responsibilities of the Accredited Center**
  4. The Contracted Research Organization shall perform the following duties:
     1. with reference to information provided by the sponsor; shall develop or support the development or implementation of a protocol for conducting ectoparasiticide/biopesticide trial which shall be submitted to the Authority (or a body appointed by the Authority) for approval;
     2. confirm in writing that he/she shall work according to the protocol by signing a declaration form as 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. maintain all records and make all data available to the Authority for the purposes of validation;
     11. forward signed Record Sheets to the Authority.
  5. 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 field trial;
  6. observe the following points related to animal welfare:
     1. give assurance that he/she has sufficient time to devote to the care and welfare of the trial animals,
     2. be responsible for animals under his/her care for the purpose of the trial and ensure that their care is maintained throughout the trial.
     3. shall ensure that the trial product is applied only to animals involved in the said trial.

# **MONITORING OF ECTOPARASITICIDE TRIALS BY THE AUTHORITY**

* 1. **Inspection of trial sites** 
     1. The Authority shall conduct inspection/ audit of trial sites.
     2. The audit shall include but not be limited to compliance with the approved protocol and Good Clinical practice.
     3. The inspections shall take place at the discretion of the Authority including but not limited to:
     4. before commencement of the trial
     5. at predetermined intervals
  2. **Reports of suspected adverse events** 
     1. The investigating institution shall report to the Authority all suspected adverse events in writing within 48 hours.
     2. The Authority shall inform the sponsor in writing about the suspected adverse drug events after causality assessment.
     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.
  3. **Progress and final trial reports** 
     1. There shall be 3-monthly progress and/or a final report as in form in (schedule 6) of this guideline.
     2. The contacted Research Organization shall submit the final report within 1 months from the date of completion of the trial.
     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.
  4. **Accountability and disposal of the investigational product** 
     1. An accountability and disposal report of the investigational product shall be submitted to the Authority within 3 months from completion of the trial.
     2. The report shall also include:
        1. date the trial started and ended;
        2. trial licence 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).
  5. **Post-trial review** 
     1. The interim and final report from the trial shall be submitted to the Authority for consideration.
     2. The format of the report shall be as provided in the protocol used in the trial.
  6. **Archiving** 
     1. The Authority, the Contracted Research Organization and the Sponsor shall archive and ensure the safety of all the documents related to the trial.
     2. The Contracted Research Organization and the Sponsor shall inform the Authority in writing prior to destroying the documents.
     3. Documents shall be retained for as long as the product is on market.

# **CONTIDITIONS FOR APPLICATION FOR A TRIAL LICENCE**

* 1. **Notification of change of information to Authority** 
     1. The trial licence 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 Licence.
  2. **Discontinuation of the trial** 
     1. The trial licence holder shall inform the Authority of any decision to discontinue the trial to which the licence relates and shall state the reason for the decision.
     2. Where a trial is discontinued, the trial licence holder shall return the trial licence to the authority as soon as possible.

# **SCHEDULES**

# **The Ectoparasiticide Trial Application Format (ETAF)**

**Introduction**

The online application for permission to conduct research in the EAC Partner States, and the paper application are provided in accordance with the national regulatory authority submission pathway for such applications.

An application for authorization to conduct a field trial shall be made by a sponsor, who must be one of the following:

• The Patent holder/Applicant and/or manufacturer

• A licensed person/Local Technical Representative of the Patent holder or the pesticide manufacturer.

# **Authorised Local Technical Representative (LTR) in EAC Partner States**

|  |  |  |  |
| --- | --- | --- | --- |
| **Member State** | **Name of Local Technical Representative** | **Address of Local Technical Representative** | **Address of Local Technical Representative** |
| Burundi |  |  |  |
| Kenya |  |  |  |
| Rwanda |  |  |  |
| South Sudan |  |  |  |
| Tanzania |  |  |  |
| Uganda |  |  |  |

In those cases, where an agent submits the field trial application, the agent must submit a power of attorney verifying his/her appointment as an agent or a letter of authorization.

Furthermore, the Guide to Field Trial Conduct indicates that based on the field trial agreement between the sponsor and the Principal investigator (PI), the competent authority will liaise with the in-country PI representing the sponsor. The PI should be an East African resident and should be licensed by a relevant body in the region.

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# **Ectoparacticide/Biopesticide Field Trial Application Form**

**Table of Content:**

Section 1: Identification of the Trial

Section 2: Basic Administrative Data on the Application

Section 3: Product to be used in the Trial

Section 4: History of previous and in-progress trials

**Section** **1. Identification of the Trial**

1.1 Title of the study

1.2 Contact person and contact details

1.3 Space for EAC code or 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 the EAC trial country.  Applicant (Local Contact):  Name date:  Signature  Designation  Principal Investigator:  Name date:  Signature:  Designation |

**E/BFTA 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 |  |  |  |

**ETAF Section 3. Product to be used in the Trial**

3.1 Investigational product

3.2 Identifier or name of investigational product (code if applicable)

3.3 Proprietary name and INN

3.4 Registration number (if product is already on the market)

3.5 Manufacturer (Include all sites)

3.6 Evidence of manufacture under conditions compliant with current codes of good manufacturing practice

3.7 Active ingredient, complete composition, potency and presentation

3.8 Release specifications and tests. Include Certificate of Analysis.

3.9 Comparator, concomitant and rescue medications (antidotes) and

3.10 Placebo

3.11 Evidence that placebo is manufactured under good manufacturing practice.

3.12 Approved package insert to be appended to application.

3.13 Details of handling trial product.

3.14 Shipping, delivery and distribution of trial product.

3.15 Details of storage requirements and arrangements where necessary and monitoring during distribution.

3.16 Details of dispensing trial products and waste disposal procedures.

3.17 Packaging and labeling of the trial products

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

**E/BTAF Section 4. History of previous and in-progress trials**

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

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 Good Clinical Practice (GCP) compliant.

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

# **The Contracted Research Organization Administrative Information**

For each site, list the following:

2.1 Address of the CRO

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

2.2 Site Identifier (Name)

Physical address: (include GPS coordinates)

Telephone & fax numbers

E-mail address

2.3 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.

2.4 Site Principal Investigator

|  |  |
| --- | --- |
| Name |  |
| Qualifications |  |
| Contact details |  |
| Physical address |  |
| Declaration of capacity & interests |  |

* 1. Site Sub-investigator and trial-specific support staff

|  |  |
| --- | --- |
| Name |  |
| Qualifications |  |
| Contact details |  |
| Physical address |  |
| Declaration of capacity & interests |  |

2.6 For animal farm sites

(a) Responsible administrator or farmer;

(b) Contact details; and

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

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

2.8 Trial Animals

2.8.1 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 |  |

2.8.2 Duration of the study

2.8.3 Estimated trial duration: Estimated date the study is due to end

2.8.4 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 was due to the trial product.

**2.9 Trial monitoring and reports**

2.9.1 Describe the safety and monitoring plan for each site.

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

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

2.9.4 When will interim reports be submitted?

2.9.5 Final report - estimated due-date?

**2.10 Insurance**

2.10.1 Provide a copy of the current insurance certificate.

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

**2.11 Description of the Trial**

2.11.1 Is the title of the trial fully descriptive?

2.11.2 Summarized rationale for this trial, including relevance to the East African region.

2.11.3 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 pesticides and this type of product

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

2.13 Trial design: describe and justify each component;

2.14 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

2.15 The treatment regimens for each group.

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

2.17 Outcomes measurements and analysis

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

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

2.20 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).

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

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

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

2.24 What is the purpose of such archiving?

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

2.26 Informed consent from animal owners.

2.27 Append a copy of informed consent from animal owners.

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

2.29 Publication policy

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



# **Format for the Ectoparasiticide Trial Protocol**

**General Introduction**

1. **Development of protocols for efficacy studies.**
2. In order to test pesticides for efficacy, the researcher must first develop the study protocol. General considerations in developing a study protocol for efficacy studies include scientific design of the study, data collection, data analysis, and reporting.

When designing a study protocol, the mode of action exhibited by the active substance e.g.

**On animal;**

Killing, repellent, anti-feeding, as well as the life cycle of the parasite e.g. length, seasonality; parasitic stages shall be taken into account;

Also consider;

* Type of pests;
* The target species of animal to which the product shall be used;
* Delivery forms of the product e.g;
  + Collars, shampoos, soaps, spot-ons and sprays for dogs and cats
  + Plunge dips, Pour-ons, back liners for cattle
  + Dusts for dogs, cats, cattle and shoats,
  + Ear dressings, wound dressings, insecticidal ear tags for cattle,
  + Spraying for cattle, and horses

**Off animals**

* Baits and traps
* Premise treatments

Internal delivery forms such as drenches, injectables, paste, gels, slow release boluses tablets and pills shall not be covered under this guideline.

This protocol shall describe steps toward the conduct of field studies only. It is the opinion of the authors of this protocol that pest control in poultry, swine, companion animals should be covered in a separate document. This is based on the knowledge that these species of animals are partly housed and pest control studies in these animals can take indoor controls on or off the animal bodies such as applications on the walls, ceiling and floor of the poultry, pigs and companion animal houses. For example, pest control in poultry should be done prior to introducing new stock of birds and immediately after selling off the old stock that have reached market weight and/or stopped laying. This measures shall be under taken concurrently with all other hygienic and disease control measures recommended in poultry farms.

For Free range poultry which are kept indoors at night; applications of pesticides on the inside of the premises shall be done, with birds being moved to another clean room during the decontamination process. Where poultry share housing with people, health ministries should be involved in the pest control measures to be undertaken.

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

**3.1 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, description, labeling, include also information leaflet of the product.

**3.2 Details of the manufacturer**

(a) Name of the manufacturer

(b) Physical address

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

(d) Country of origin

**3.3 Identification of the trial**

(a) Title of the trial

(b) Version

**3.4 Aim of the Trial**

a) State the objective(s)

b) Rationale of trial.

**3.5 Trial sites**

At least two sites in two different geographical zones in a minimum of two East African Partner States shall be considered.

**3.6 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 each country where the trial shall be conducted.

(a) Trial initiation

(b) Trial completion

**3.7 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

**3.8 Sponsor**

(a) Name

(b) Address

(c) Telephone numbers, email, Fax

**3.9 Trial animals**

(a) Species

(b) Identification number of animal/unit details

(c) Number of animals involved in the trial. There shall be an appropriate justification for the use of animals, such that the field trials only, utilise the minimum number of animals required to obtain valid data.

(d) Sex

(e) Age

(f) Weight

**3.10 Husbandry**

Complete description of management systems

**3.10.1 Husbandry**

1. All animals enrolled in the study should be fed palatable, uncontaminated diets that meet their nutritional and behavioral needs;
2. Feeds should be stored in vermin-proof containers, at appropriate temperature and humidity, in clean areas that are easy to sanitise;
3. All Trial’s animals should have access to potable and uncontaminated drinking water. The animal attendants should frequently check watering devices to ensure appropriate maintenance, cleanliness and operation;
4. Stocks should be rotated so that oldest feeds are used first and pet animals should be fed freshly prepared foods each day.
5. Poultry, pigs and other animal feeders should be located to allow easy access and to minimize contamination with urine and fecal material.
6. For housed animals; ensure that animals have enough space and feeding points to minimize competition and ensure access for all animals.
7. The interior of animal houses should be kept clean and sanitized by removing soiled beddings and replacing with fresh materials on regular basis. This is important in poultry houses to keep the birds clean and dry and to lower ammonia levels.
8. Wetness, environmental temperatures and humidity, will determine the frequencies of changing beddings. Also consider the types of ventilations, fecal and urinary output, the species and number of animals under trails;
9. Aim at attaining a healthy environment for the animals enrolled in the study.
10. Disposals of Hazardous wastes, conventional and biological wastes should be done regularly, safety and in appropriate manner;
11. Except for pests under investigations; all animal facility should have a pest control program to prevent, control or eliminate the presence of or infestation by pests.

**3:10.2 Housing**

All the study animals shall be housed under conditions that provide sufficient space as well as supplementary structures and resources required to meet physical, physiological and behavioral needs. The type of facility used must meet the appropriate macro and micro-environment requirements of the housed animal.

1. Social animals should be housed in stable pairs or groups unless they must be housed alone for experimental reasons (should be justified in protocol) or because they are socially incompatible;
2. The primary enclosure should be secure to prevent escape and made of durable and from nontoxic material. Animals should have adequate bedding material for species-specific absorb urine and feces and or structures for resting and sleeping;
3. Animals should be housed within temperature and humidity ranges appropriate for the species. There shall be daily monitoring and documentation of daily environmental parameters such as temperature, humidity, ventilation, air quality, illumination and noise;
4. Space size of primary enclosure should be well ventilated and appropriate for different species of animals enrolled in the study;
5. Lighting should be diffused throughout an animal holding area and provide sufficient illumination for the animals’ well-being, good housekeeping practices, adequate animal inspection and safe working conditions for personnel.
6. Noise control should be considered in facility design and operation.
7. Noisy animals, such as dogs, swine, goats should be housed away from quieter animals.

**3.10.3 Animal Health**

Animals used in field trials may experience health related concerns, pain and distress during the study procedure. It is the responsibility of the entire team conducting the study procedures to treat the sick animals, or reduce, minimize or eliminate pain and distress in animals enrolled in the field trials. The principal Investigator shall ensure that the team comprises of adequate number of qualified veterinarians, and appropriate specialties for each species of animals used in the field trails.

To be effective in providing clinical care, the veterinarian shall be familiar with the species and have access to records.

**The Principal Investigator shall;**

1. Ensure that a veterinarian with appropriate specialization in the species of animal under study is involved in establishing, reviewing, and overseeing animal health records;
2. National laws and regulations regarding the use and disposal of veterinary drugs are complied with;
3. Put in place SOPs for reporting all health related issues;

d) Put in place procedures for emergency veterinary care throughout the trails period;

g) Put in place measures to ensure that risks associated with infectious agents and biohazardous materials are minimized.

**3.10.4 Test facilities, equipment, and materials**

There shall be-

1. in case of large animals, adequate pasture for continued exposure to re-infestation;
2. suitable handling facilities for handling the animals during ectoparasiticide counts;
3. specialized facilities that ensure and maintain animal welfare, designed for particular species under the study;
4. facility information including the location shall be provided as part of the submission to the competent authority.
5. suitable equipment and measuring containers for accurate measurements and application of the trial formulation as well as that of the positive control formulation; and
6. protective clothing, appropriate to the type of formulation under test.

**3.11 Description of the trial**

For all **On animal**/contact applications; 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.

This approach shall not be used where mode of delivery is indoor spraying., but another method shall be utilized.

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.

**3.12 Demonstration of efficacy**

(a) Methods used for the assessment of efficacy shall berelevant 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

**3.13 Efficacy calculations**

A description of the method used to calculate efficacy of the product shall be provided-(see the guidelines on demonstration of efficacy of ectoparasiticides during conduct of ectoparasiticide trials in the EAC)-Code PSS/1/1/21/….

**3.14 Suspected adverse event**

There shall be in place -

(a) methods of recording and reporting suspected adverse events or reactions; All serious adverse events and unexpected events shall be reported. Reporting requirements specifically include:

1. All serious adverse events regardless of whether the event is related to the intervention or not;
2. Rate or frequency of each event;
3. Rationale for listing each event;
4. All serious adverse events and unexpected events must be reported to the Competent authority, the investigator and the investigational veterinarian as soon as possible and in any case no later than seven (7) calendar days of becoming aware of the event.
5. A detailed report of the serious adverse event and unexpected event should be submitted within seven (7) calendar days from the date it is reported to the competent authority.

b) All other reportable adverse events should be reported to the competent authority as soon as possible and in any case not later than fourteen (14) calendar days. These include:

* When criteria for stopping or pausing a study as stipulated in the protocol are met.
* Any event stipulated in the protocol as reportable to the regulatory bodies.

**3.14.1. Format of reporting events**

All reportable events including serious adverse events, adverse events, unexpected events protocol violations and deviations should contain the following information:

a) Title of the study.

b) Name of researcher.

c) Institution of affiliation.

d) Date of report.

e) Date(s) when events, violation(s) or deviation(s) occurred.

f) Brief description of the event.

g) Any effect it might have on the study.

h) Whether the events arise from the violation or deviation from the protocol.

i) Management and follow up of adverse events, violation(s) or deviation(s) and steps to avoid recurrence. The Researcher shall notify the collaborating institution, competent authority within the specified timelines.

(b) provisions of antidotes if any.

**3.16 Evaluation of results**

1. A description of data management procedures shall be provided.
2. A description of the statistical methods to be employed, including timing of any planned interim analysis.
3. The number of animals to be enrolled. In multicenter trials, the numbers of animals projected for each trial site should be specified.
4. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
5. Statistical methods and considerations (methods for data analyses and evaluation of results). Any statistical significant difference between the treated and the control group shall always be interpreted in terms of biological and clinical significance.
6. Criteria for the termination of the trial;
7. Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
8. The selection of participants to be included in the analyses (e.g. all randomized participants, all dosed participants, all eligible participants, evaluable participants).
9. Participants withdrawn from the trial shall be indicated and the reasons for withdrawal shall be indicated.
10. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
11. Procedure for accounting for missing, unused, and spurious data.

**3.17 INFORMED CONSENT PROCESS**

**3.17.1 General Requirement for Informed Consent Process**

It is important for a researcher to obtain informed consent from the animal owners including farmers, breeders and institutions, from where trial’s animals are sourced. No animals shall be involved in a study unless the researcher has obtained prior informed consent from the relevant individuals/institutions that own the animals. A researcher shall ensure that the animal owner or institution has sufficient understanding of the relevant information and knows the consequences of permitting the use of their animals in the trials and be given opportunity to consider whether or not to allow participation of their animals.

All communications with the animal’s owner or their representatives shall be in in a language understandable to all the parties. The researcher, sponsor, or its agents shall be held liable of any loss or damage during the field trial.

**3.17.2 Key components of the Informed Consent Form**

The information to be included in the informed consent form shall include the following:

1. A statement that the trial has been approved by a competent authority in the EAC Partner State where it is to be conducted;
2. Trial description and the estimated duration;
3. The approximate number of animals to be involved in the trial;
4. A description of any reasonably foreseeable risks or discomforts that the animal may experience.

c) The benefit of the trial.

f) Names and contact details of individual(s) who should be contacted at any time in case of questions about the animal welfare, including the sponsors and the institution of affiliation for the researchers;

g) An assurance that participation is voluntary;

e) A details about compensation and veterinary treatment available if injury occurs;

i) The nature, form and extent of compensation for loss of production, injury or deaths.

l) Provision for a witness at appropriate to the informed consent process, especially for illiterate animal owners.

**3.17.3 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.

*A statement explaining the consequences of the animal owner’s decision to withdraw from the study*. The study animal may be withdrawn at any time without further notice. However, animal owners should be provided with a description of the procedures that are to be followed in order to give notice of their animals’ withdrawal.

A statement that significant new findings obtained during the course of the study, whether by the researchers or others that may relate to the animal owners’ willingness to continue his or her participation, shall be provided to the animal owner in a timely manner.

**3.17.4 Documentation of Informed Consent Process:**

a) The Principal Investigator shall document the informed consent process.

Animal owners or their representatives shall sign/mark/thumbprint an informed consent form approved by a competent authority.

A copy of the signed consent form shall be offered to the animal owner or his/her representative.

b) The animal owner or their representative must be given sufficient time to read the consent form before signing or placing his or her thumbprint on the form indicating that he/she has read and understood and agrees to participate in the study.

c) The consent form shall be read to illiterate animal owners.

d) Verbal consent may be obtained in studies that present no more than minimal risk or in studies where for justifiable reasons written consent may not be feasible. However, verbal consent must be documented.

e) The competent authority reserves the right to determine when verbal informed consent may be appropriate and acceptable.

**3.18 Environment Impact Assessment (EIA)**

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



# **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 (State the name of the country in the EAC).

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 Authority in the East African Partner State of ………………………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 National Authority and other government bodies as may be required. I will provide the national authority 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/Provincial 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 pesticide products.

Initials:……………………………………

SIGNED ……………………..DATE ……………………………………

WITNESS:……………………NAME ……………………..DATE ………



# **Format for Labelling Trial Products**

**Outer/carton labels & Unit Pack**

5.1 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 retest date | ? | ? |
| Expiry date | ? | ? |
| For Trial Use Only |  |  |
| Name and address of manufacturer or final release or product owner (corporate 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.



# **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

10. Trial animals; Species, Sex, Age, Productive status

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 Head National Pesticides Registration Authority

Address

Tel:

INTERIM OR END OF STUDY SUMMARY REPORT <Whichever applicable>

< Trial Protocol Title and Protocol Number>

<EAC product code/national 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 discontinuation: <insert number>

Reasons 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 pesticide supplies collected back from site: < insert date>

Last batch of pesticide supplies sent back to < originating site> for destruction: <insert date>; if local destruction, attach copy of the destruction certificate.

List of any changes in trial personnel – including full Curriculum Vitae and declaration

List of monitor and audit reports to date.



# **Information to be given to the Contracted Research Organisation to aid them in developing the Trial Protocol**

* 1. **Finished Product**

Description (physical characteristics):

Composition (Complete Formula)

Active Ingredient

|  |  |
| --- | --- |
| Active Ingredient(s): |  |
| Content |  |

Other Ingredients (adjuncts, excipients, preservative, color, smell, etc):

|  |  |
| --- | --- |
| Name of Other Ingredient(s) |  |
| Content |  |

Packing or pack size (brief)

* 1. **Manufacture of Product**

Complete batch manufacturing master formula

|  |  |
| --- | --- |
| Name of Ingredients (active and otherwise) |  |
| Quantities used per batch |  |

Manufacturing process:

Brief description and principles.

* 1. **Quality Control**

State whether quality control is done in part or solely by the manufacturer’s own quality control department or an external laboratory.

If quality control tests are done by an external laboratory, state:

name and address of the laboratory (where applicable);

tests done by the external laboratory (where applicable);

reasons why the tests are not done by the manufacturer.

* 1. Specifications for ingredients, active and otherwise

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

Manufacturer and country of origin

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 |  |

* 1. **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:

* 1. **Stability of Product:**

Storage condition must be included on the label.

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.



# **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 the East African Partner State of:

Burundi paste shape

Kenya

Rwanda

South Sudan

United Republic of Tanzania

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



# **Required Documents at submitting in Application for Conduct of Ectoparasiticide Trials**

|  |  |
| --- | --- |
| Item | Requirement |
| Fees | Proof of payment |
| Material 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 national approval authority. |
| 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 | Data on dosage form and any other relevant information |
| Appendix .. | Clinical Trial Agreement between the Sponsor and the Principal Investigator |
| Appendix 14 | Other supporting documents. |

Note:

Certificate of Good Manufacturing Practice (GMP) for the investigational product or statement on GMP from the manufacturer/re-packer (whichever is more relevant).

• The GMP certificates or other documents must be issued by an authority recognised by EAC Partner State.

• Or the statement on GMP can be issued by the Quality Assurance Department where the product is manufactured.

• For local product, the manufacturing licence is required.

• For a comparator product, the following is required:

i) a GMP certificate

ii) If not available, one of the following can be submitted:

• Approval letter from the regulatory authority

• Annual Registration of Pesticide Establishment

• Package insert

iii) For a repacked product, a statement of GMP must be submitted by the re-packer.

Approvals of study protocols should be submitted along with the Trial Application to the National Authority.

1. **Required Documents by the Authority Inspector at the Port of Entry for Conduct of Ectoparasiticide Trials**

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 national authority letter of approval of trial |  |  |
| 2. | CoA to 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 |  |  |
| 3. | Results of physical and analytical tests |  |  |
| 4. | A copy of valid Certificate of Manufacture issued by the competent Regulatory Authority in the country of origin |  |  |
| 5 | Application device included (if applicable) |  |  |
| 6 | The label clearly indicate Labeling: outer packaging, immediate container |  |  |
|  | That the product is trial material, e.g. “For use in trial only” |  |  |
|  | Product name or unique code (if blinded) |  |  |
|  | The Storage temperature is stated |  |  |
|  | The Storage conditions indicated (e.g. protection from light) |  |  |
|  | The Batch number is stated |  |  |
|  | The Date of manufacture is stated |  |  |
|  | The Expiry date is stated |  |  |
|  | Details of Sponsor`s contacts is included |  |  |
| 7 | The physical condition of the consignment is acceptable |  |  |

# **References:**

For additional information about the harmonized test guidelines and to access the guidelines electronically, please go to <https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>

Document Revision History

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date of revision | Revision number | Document Number | Author(s) | Changes made and/or reasons for revision |
|  | 0 |  |  |  |
|  | 1 |  |  |  |
|  | 2 |  |  |  |

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