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**

1. 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
2. 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.
   1. **Details of the manufacturer**

(a) Name of the manufacturer

(b) Physical address

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

(d) Country of origin

* 1. **Identification of the trial**

(a) Title of the trial

(b) Version

* 1. **Aim of the Trial**

1. State the objective(s)
2. Rationale of trial.
   1. **Trial sites**

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

* 1. **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

* 1. **Investigating institution**

1. Name of the investigating institution
2. Name of the investigator

(c) Curriculum Vitae and attached testimonials

(d) Address

(e) Telephone number(s)

(f) Email(s)/Fax

* 1. **Sponsor**

(a) Name

(b) Address

(c) Telephone numbers, email, Fax

* 1. **Trial animals**

(a) Species

(b) Identification number of animal

(c) Number of animals involved in the trial

(d) Sex

(e) Age

(f) Weight

* 1. **Husbandry**

Complete description of management systems

* 1. **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.

1. Trial design (e.g. randomized controlled trial, open- label parallel group, cross-over technique)
2. Criteria for inclusion of potential trial animals and exclusion of some
3. Group allocation
4. Treatment procedure including other treatments these animals will receive during the study irrespective whether there is interaction with the product under investigation.
5. 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).
6. The applicant is required to justify the group size and it is recommended to seek the advice of a statistician.
7. Ectoparasite count according to stages of engorgement and species shall be indicated.

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

* 1. **Demonstration of efficacy**

1. Methods used for the assessment of efficacy shall be relevant for the parasite species involved and for the level of efficacy to be demonstrated.
2. Methods used for the assessment of efficacy shall be justified
   1. **Efficacy calculations**

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

* 1. **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. suitable equipment and measuring containers for accurate measurements and application of the trial formulation as well as that of the positive control formulation; and
4. protective clothing, appropriate to the type of formulation under test.
   1. **Suspected adverse event**

There shall be in place -

1. methods of recording and reporting suspected adverse events or reactions; and
2. provisions for dealing with complications for example anti dots.
   1. **Evaluation of results**
3. A description of data management procedures shall be provided.
4. 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.
5. Participants withdrawn from the trial shall be indicated and the reasons for withdrawal shall be indicated.

**3.17 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.

**3.18 Environment Impact Assessment (EIA)**

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