

ANTHELMINTICS FOR CATS AND DOGS: SPECIFIC REQUIREMENTS

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Additional Notes	This note for guidance provides specific requirements for the establishment of the efficacy of anthelmintics in Cats and Dogs. General requirements are described in the note for guidance: <i>Anthelmintics: General Requirements</i> .

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ANTHELMINTICS FOR CATS AND DOGS: SPECIFIC REQUIREMENTS

1. INTRODUCTION

- 1.1 The note for guidance on general requirements to establish the efficacy of an anthelmintic apply and include the following test phases:
- Indication of mode of action
 - Titration of dose trials
 - Dose confirmation trials
 - Clinical trials
- 1.2 The efficacy of an anthelmintic for cats and dogs may be determined by a controlled test or a critical test.¹⁰

2. PRECLINICAL STUDIES

2.1 Selection of animals

- 2.1.1 The animals used in these tests must be healthy, except regarding parasitic infection, and appropriately vaccinated. They may be of either sex and of any breed, age or size, although a specific age is recommended in some cases (see Table 1).
- 2.1.2 Anthelmintic tests may be carried out using either naturally or artificially infected animals; artificially infected animals should bear adequate worm burdens. There are certain parasites for which only artificial infection is acceptable.
- 2.1.3 In general, when animals are infected experimentally, at least one trial should be carried out using naturally infected animals for each parasite to be studied. For studies other than field trials, experimental infection only is acceptable for the following:
- Spirocerca lupi*, *Capilaria plica*, *Capilaria aerophila*, *Mesocestoides spp.*, *Echinococcus granulosus*. If the animals need to be deparasitised before being experimentally infected, this must be done using a product which is chemically unrelated to the one being studied, or sufficiently well in advance to avoid interfering with the study.
- The groups of animals should be as homogeneous as possible as regards breed, sex, etc.. All the animals in the same group should have similar parasite burdens and be treated on the same day and all sacrificed at a time justified by the investigator.
- 2.1.5 All necropsy examinations must be carried out on the day of sacrifice unless otherwise justified.
- 2.1.6 By a statistically acceptable method of random selection, the animals should be divided into various groups; some groups will be treated and others not. To give statistical

¹⁰ See Annex 1 to the note for guidance on *Anthelmintics: General Requirements*.

validity to the efficacy of a product each group must contain a sufficient number of animals. The applicant must justify the number used.

2.2 Feeding

Under the investigator's responsibility, the animals should be given a nutritionally balanced ration in accordance with their age, sex, breed, etc.. The animals should be given sufficient time, at least 5 days, to adjust to the experimental diet.

Where the test product is administered in the feed, the daily intake should be recorded for each animal, before and after the test, and note taken of any loss of appetite. Data relating to animals which do not ingest the whole ration may not be taken into consideration when the efficacy of the product is evaluated.

2.3 Accommodation

The animals should be given sufficient time, at least 5 days, to adjust to their environment and all animals should be looked after in the same way.

They should be kept in sufficiently large cages, preferably one animal per cage.

Care should be taken to avoid reinfestation of treated animals and the environmental dissemination of the parasite, particularly when the period of trial is extended. Such reinfestation may make interpretation of the results of treatment difficult.

3. CLINICAL TRIALS

3.1 The aim is to determine the efficacy of the product in the field, under different environmental and husbandry conditions. the trials should be carried out in at least two different geographical areas.

3.2 The recommended formula, dose and route of administration should be used.

3.3 The appropriate number of animals should be chosen in each case; a control group should be set up (number of animals in control group: at least 10% of total).

3.4 Relevant samples should be collected daily, or at justified intervals. A record should be kept of the animals' well being, to determine the side-effects and any adverse reactions. If possible, statistical analysis of the results should be carried out.

3.5 Where public health may be compromised by reason of a clinical trial, special precautions should be taken, e.g. for Echinococcus 100% efficacy is required.

4. PRODUCTS FOR TOPICAL USE

When evaluating the efficacy of products for topical use the general rules should be observed and account taken of other factors such as:

- Climatology: rainfall, sunshine, etc.;
- Length of hair: (short: less than 1 cm; long: over 6 cm);
- Oral toxicity.

5. MOST COMMON HELMINTHS IN THE EEC

The list of parasites given below is not exhaustive. The applicant must justify efficacy against the parasites indicated on the product labelling.

5.1 Trematodes

Dogs and Cats:

- *Alaria alata*
- *Opisthorchis tenuicollis*

5.2 Cestodes

Dogs and Cats:

- *Taenia hydatigena*
- *Taenia pisiformis*
- *Hydatigena Taenia taeniaeformis*
- *Echinococcus granulosus*
- *Echinococcus multilocularis*
- *Dipylidium caninum*
- *Diphyllobothrium latum*

Dogs:

- *Taenia ovis*
- *Multiceps multiceps*
- *Multiceps serialis*
- *Mesocestoides lineatus*
- *Mesocestoides corti*

5.3 Nematodes

Dogs and Cats:

- *Ancylostoma caninum*
- *Uncinaria stenocephala*
- *Toxocara canis*
- *Toxocara cati*
- *Toxascaris leonina*
- *Strongyloides stercoralis*
- *Filaroides osieri*
- *Capillaria aerophila*
- *Capillaria plica*
- *Capillaria hepatica*
- *Trichinella spiralis*

Dogs:

- *Angiostrongylus vasorum*
- *Trichuris vulpis*
- *Spirocerca lupi*
- *Dirofilaria immitis*

Cats:

- *Ancylostoma tubaeforme*
- *Aelurostrongylus abstrusus*

TABLE 1

Age of animals

In general all animals at least 6 months old are acceptable. For some species, younger animals may be preferable:

- | | |
|--|----------------------|
| - Strongyloides stercoralis var. canis | - less than 6 months |
| - Ancylostoma caninum | - 6 to 12 weeks |
| - Ancylostoma tubaeforme | - 6 to 12 weeks |
| - Uncinaria stenocephala | - 6 to 12 weeks |
| - Toxocara canis | - 2 to 6 weeks |
| - Toxocara cati | - 2 to 6 weeks |
| - Toxascaris leonina | - 2 to 6 weeks |
| - Dipylidium caninum | - 3 months or more |
| - Mesocestoides spp. | - 8 weeks or more |