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| D:\nda\2016\memo\nda logo.jpg | National Drug AuthorityPlot No. 46 - 48 Lumumba Avenue,P.O. Box 23096, Kampala, Uganda.email: [ndaug@nda.or.ug](mailto:ndaug@nda.or.ug); website: [www.nda.or.ug](http://www.nda.or.ug)Tel: +256-414-255665, +256-414-347391/2 |  |
| 8. Information to be given to the Contracted Research Organisation to aid them in developing the Ectoparasiticide Trial Protocol | | |

**8.1 Finished Product**

1. Description (physical characteristics):
2. 1.2 Composition (Complete Formula)
3. Active Ingredient

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

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

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

1. Packing or pack size (brief)

**8.2 Manufacture of Product**

1. Complete batch manufacturing master formula

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

1. Manufacturing process:
2. Brief description and principles.

**8.3 Quality Control**

1. State whether quality control is done in part or solely by the manufacturer’s own quality control department or an external laboratory.
2. 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.

1. Specifications for ingredients, active and otherwise

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

1. 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 |  |

8.4 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:**
     1. Storage condition must be included on the label.

8.5.2 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.