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| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **R:\Logos\VMD Logos\4 Detailed Colour - light green.png** |  | **Veterinary Medicines Directorate**  Woodham Lane, New Haw  Addlestone, Surrey  KT15 3LS  United Kingdom  Tel: +44 (0)1932 336911  Search for VMD on GOV.UK |   **APPLICATION FOR AN ANIMAL TEST CERTIFICATE (TYPE A or B)**  **USING A PHARMACEUTICAL PRODUCT**  **An incomplete application form may delay the application process.**  *Where a section of the application form refers to data supplied within the data package, please clearly indicate the location of this data within the data package, e.g. attachment / PDF name, page number etc.*  **Further guidance about this application type is available on GOV.UK**  **SECTION 1 – ADMINISTRATIVE DETAILS** |

**1.1 Product Name:**

**1.2** **Name and Address of Proposed ATC Holder:**

Company Name:

Address:

**1.3** **Name and Address of Sponsor[[1]](#footnote-1) (if different to 1.2 above):**

Company Name:

Address:

Email Address:

Telephone No:

**1.4** **Contact Details for this Application:**

Name:

Email Address:

Telephone No:

**1.5** **Invoice Details:** Email address of where the invoice should be sent to.

Email Address:

**1.6** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 1.4 above).

Email Address:

**SECTION 2 – APPLICATION DETAILS**

**2.1 Application Type – A or B**

Type:

**2.2 Previous ATC Authorisation No. (If applicable):**

**2.3 Name and address of previous ATC holder (if applicable, and if different to the holder of 2.2 above):**

Name:

Address:

**2.4 Details of any UK Marketing Authorisations (same formulation):**

**Vm No:**

**Other details:**

**2.5 Details of any other EU or EEA Marketing Authorisations:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member\* State** | **MA No. (equivalent to Vm no. in UK)** | **Species** | **Dosage / Route** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |

\* Type A applications only:

* please highlight the EU or EEA authorised product being used in this study
* please attach a copy of the marketing authorisation and SPC for the product (in English translation)

**2.6 Details of any third country (USA, Canada, Japan, New Zealand and Australia only) Marketing Authorisations:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member State** | **MA No. (equivalent to Vm no. in UK)** | **Species** | **Dosage / Route** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |

Please attached a copy of the marketing authorisation and SPC for the product (in English translation)

**2.7 Please confirm that proposed label(s) and package leaflet(s)\*\* have been provided for the test article and the control or placebo products.**

**Yes:**       **No:**

**\*\*Documents should be compliant with the UK 'Product Literature Standard'.**

**2.8 Please confirm that the trial protocol and owner consent form have been submitted with this application form.**

**Yes:**       **No:**

**2.9 If any trial procedures are covered by A(SP)A, the Home Office Project License number should be provided:**

**SECTION 3 – TRIAL DETAILS**

**3.1** **Nature and purpose of the test (objectives):**

**3.2** **Target Species (only one per trial):**

**3.3** **Indication(s) or outcomes / endpoints to be investigated:**

**3.4 Details of the pharmaceutical form / method of administration / dose rate / duration of administration:**

1. Investigational treatment (test article):
2. Positive control:
3. Negative / placebo control:

**3.5 Maximum no. of animals treated with:**

1. Investigational treatment (test article):
2. Positive controls:
3. Negative controls:
4. Placebo treated controls:

**3.6** **Estimated duration of trial:**

**3.7 Description of eligibility criteria for animals:**

1. Inclusion criteria:
2. Exclusion criteria:

**3.8 Description of safety monitoring (provision for monitoring, investigating and reporting suspected adverse reactions; details of clinical assessments, blood test, etc):**

**3.9 Name and qualifications of the overall test Monitor (see VICH guideline on Good Clinical Practices for definition of Monitor):**

**3.10 Name and qualifications of person responsible for pharmacovigilance:**

**3.11 Details of the Investigator(s), if known†(see VICH guideline on Good Clinical Practices for definition of Investigator):**

**3.12 Details of test site(s) (if known††) indicating the identity of the named Investigator with responsibility at each individual test site where multiple sites are named:**

†If not available, any additional Investigator details should be submitted for consideration once known; this should be by way of an ATC variation application.

**††**If not available, an estimated maximum number of sites should be provided with confirmation of the exact number plus details given in writing before the trial starts; please note if final numbers exceed the estimated maximum a variation must be submitted for consideration before the trial commences.

**SECTION 4 – CHEMISTRY AND MANUFACTURING INFORMATION**

**4.1** **Is the product to be trialled already authorised as a veterinary medicine in an EU member state?**

**Yes (go to 4.3):**       **No (go to 4.2):**

**4.2** **Is the product to be trialled already authorised as a human medicine in an EU member state?**

**Yes (go to 4.3):**       **No (go to 4.4):**

**4.3** **Is the authorised veterinary or human product to be administered in accordance with the EU or EEA Marketing Authorisation, i.e. unchanged in the authorised packaging?**

**If yes,**     , please provide a signed statement to confirm that the dosage form to be trialled will be used in conformance with the EU Marketing Authorisation. No further information is required unless a placebo product is to be used. In this case, please complete section 4.5, 4.6 and 4.9 for the placebo only.

**If no,**     , please indicate deviations from MA and provide supporting data under relevant headings below.

**4.4** **Is the active substance from the proposed source already included in products authorised in the EU or EEA for use in animals or humans?**

**Yes (provide details):**

**Animal or Human:**

**Go to 4.5**

**4.5** **Qualitative and Quantitative Particulars (provide details for all strengths of active and / or placebo products):**

**Active Substance:**

|  |  |  |
| --- | --- | --- |
| **Ingredients** | **Unit Composition** | **Grade** |
|  |  |  |
|  |  |  |

**Other Substances:**

|  |  |  |
| --- | --- | --- |
| **Ingredients** | **Unit Composition** | **Grade** |
|  |  |  |
|  |  |  |

**Materials removed during manufacture:**

|  |  |  |
| --- | --- | --- |
| **Ingredients** | **Unit Composition** | **Grade** |
|  |  |  |
|  |  |  |

**4.6 Pack Details:**

1. Size:
2. Container / Closure:
3. Dosing Device:

**4.7 Manufacture of Finished Product:**

1. Finished product manufacturer’s name and address:

1. Assembler’s name and address:

1. Outline of manufacture and in-process control:

**4.8(a) Starting Materials (Control of Active Substances):**

1. Active substance manufacturer’s name and address:
2. Active substance specification -

either:

* Reference the pharmacopoeial monograph
* Reference a source already authorised in the EU for use in animals or humans, or
* Tabulate the specification below

|  |  |  |
| --- | --- | --- |
| **Test** | **Limit** | **Test Method** |
|  |  |  |
|  |  |  |

1. Active substance manufacture – evidence of structure and impurities:

**4.8(b) Starting Materials (Control of Other Substances):**

1. Please provide specifications for non-pharmacopoeial substances:

**4.8(c) Starting Materials (TSE Compliance):**

1. Please provide a declaration and format:

**4.9 Finished Product Release Specification:**

|  |  |  |
| --- | --- | --- |
| **Test** | **Limit** | **Test Method** |
|  |  |  |
|  |  |  |

**4.10 Stability and Shelf-Life:**

* Please provide supporting stability data

1. Shelf-Life and storage conditions:

1. In-use shelf-life (if appropriate):

**SECTION 5. HUMAN SAFETY INFORMATION (USER AND CONSUMER):**

(All questions apply to both Type A and Type B applications)

**5.1 Is the product to be tested already authorised in the UK for the same species and with the same posology?**

**Yes:**       **No (go to 5.2):**

If yes: Provide and indicate location of data in table below: S.1

**5.2 Is the product to be tested already authorised in the UK for the same species and with different posology?**

**Yes (companion animal):**       (Provide and indicate location of data in table below: S.1 and S.13)

**Yes (food-producing animal):       (**Provide and indicate location of data in table below: S.1, S.11, S.13, R.1, R.2, R.3, R.6)

**No (go to 5.3):**

**5.3 Is the product to be tested:**

1. **already authorised in the UK for a different species (including man)?**
2. **already authorised elsewhere in the EU for the same or different species?**

**Yes (companion animal):**       (Provide and indicate location of data in table below: S.1 and S.13)

**Yes (food-producing animal):       (**Provide and indicate location of data in table below: S.1, S.11 or S.12, S.13, R.1, R.2, R.3 or R.4, R.6)

**No (go to 5.4):**

**5.4 Does the product to be tested contain active substances which are already used in veterinary medicine in the EU?**

**Yes (companion animal):**       (Provide and indicate location of data in table below: S.1 and S.13)

**Yes (food-producing animal):       (**Provide and indicate location of data in key below: S.1, S.11 or S.12, S.13, R.1, R.2, R.3 or R.4, R.6)

**No (go to 5.5):**

**5.5 Does the product to be tested include a new active substance in veterinary medicine in the EU?**

**Yes (companion animal):**       (Provide and indicate location of data in table below: S.2 – S.10, S.13)

**Yes (food-producing animal):       (**Provide and indicate location of data in key below: S.2 – S.10, S.11 or S.12, S.13, R.1, R.2, R.3 or R.4, R.6)

**No:**       **(State existing uses of active substance, if any):**

**5.6 Disposal or fate of test food producing animals (not intended to enter the human food chain for food):**

| **Ref.** | **Item** | **File name** |
| --- | --- | --- |
| S.1 | MA and SPC of authorised product |  |
| S.2 | Summary of pharmacodynamic studies |  |
| S.3 | Summary of pharmacokinetics studies in laboratory animals |  |
| S.4 | Summary of single dose toxicity studies |  |
| S.5 | Summary of repeated dose toxicity studies |  |
| S.6 | Summary of target species tolerance studies |  |
| S.7 | Summary of reproductive toxicity studies |  |
| S.8 | Summary of mutagenicity studies |  |
| S.9 | Summary of carcinogenicity studies |  |
| S.10 | Summary of other studies as appropriate, e.g. microbiological effects, neurotoxicity, immunotoxicity, observations in man, etc. |  |
| S.11 | Statement of EU ADI |  |
| S.12 | Proposal for ADI for trial |  |
| S.13 | User risk assessment |  |
|  |  |  |
| R.1 | Summary of pharmacokinetic studies in the target species |  |
| R.2 | Summary of residues depletion studies |  |
| R.3 | Statement of EU MRLs |  |
| R.4 | Proposal for trial MRL |  |
| R.5 | Statement of existing withdrawal period |  |
| R.6 | Proposal for withdrawal period for trial |  |
|  | Existing uses of new active substances, if any |  |

**SECTION 6 – ENVIRONMENTAL SAFETY INFORMATION**

This section applies to Type B applications for food producing animals. No environmental safety information is required for Type A and B applications for companion animals.

**6.1 For food-producing species excl. fish:**

Please provide an environmental risk assessment specific to the trial you intend to carry out. The assessment should set out to demonstrate that exposure of the environment will not be extensive and should consider the number of animals in the trial, the number of trial sites, and the dose and duration of treatment

Please tick appropriate box -

**Included (File name):**

**N/A (Give reason):**

**6.2 For fish, where Scottish Environment Protection Agency (SEPA) or the Environment Agency (EA) has already authorised the trial:**

Please provide evidence of SEPA/EA authorisation for the sites and numbers of fish to be used in the trial.

Please tick appropriate box -

**Included (File name):**

**N/A (Give reason):**

**6.3 For fish, where there is no authorisation from either the Scottish Environment Protection Agency (SEPA) or the Environment Agency (EA):**

If no SEPA/EA authorisation has been obtained, please provide an environmental risk assessment. For more information, please contact a member of the VMD Human & Environmental Safety team via the VMD main switchboard 01932 336911.

Please tick appropriate box -

**Included (File name):**

**N/A (Give reason):**

**6.4 Disposal of unused product and empty containers:**

**SECTION 7 – TARGET SPECIES SAFETY**

**7.1** Please provide target species safety data for all applications, EXCEPT Type A where an existing EU or EEA authorisation is for the same species and the same posology

**SECTION 8 – EFFICACY INFORMATION**

**8.1** For ALL applications, please provide evidence that there is reasonable expectation that the test product will produce the desired effect. NB. Although detailed efficacy data are not required, brief details of pilot studies etc. may be submitted to provide the necessary justification.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section 9 – Declaration**  I / We apply for the application as described above. I / we confirm that the information given in support of this application is correct at the time of submission.  I / We apply for an ATC and undertake:   * to abide by the terms and conditions of any ATC issued in response to this application * to ensure that Informed Owner Consent is obtained for animals participating in the trial * to comply with the pharmacovigilance reporting requirements   I / We also undertake to inform the VMD of:   * any matter coming to our attention which might affect the safety in use of the product * the discontinuation of the test with an explanation | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **If any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation.** | | | | |

1. The Sponsor is the individual, company or organisation who takes responsibility for the initiation, management and, usually, the financing of the clinical trial. [↑](#footnote-ref-1)