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| **R:\Logos\VMD Logos\4 Detailed Colour - light green.png** |  | **Veterinary Medicines Directorate**Woodham Lane, New HawAddlestone, SurreyKT15 3LSUnited KingdomTel: +44 (0)1932 336911Search for VMD on GOV.UK |

**APPLICATION FOR A NEW ANIMAL TEST CERTIFICATE (ATC)****USING A PHARMACEUTICAL PRODUCT - TYPE A or B APPLICATION****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 Name of Test Product:**

**1.2** **Name and Address of Proposed ATC Holder[[1]](#footnote-1):**

 Name:

Company Name:

 Address:

Email Address:

Telephone No:

**1.3** **Name and Address of Sponsor[[2]](#footnote-2) (if different to 1.2 above):**

 Name:

 Address:

Email Address:

 Telephone No:

**1.4 Application Type (A or B)**

Type:

**1.5** **Contact Details for this Application:**

 Name:

 Email Address:

Telephone No:

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

 Email Address:

**1.7** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 1.5 above).

 Email Address:

**1.8 Previous ATC Authorisation No. (if applicable[[3]](#footnote-3)):**

**1.9 Name and address of previous ATC holder (if applicable):**

Name:

Address:

**1.10 Please confirm that proposed label(s) and package leaflet(s)\*\* have been provided for the test product and the control or placebo products:**

**Yes:**

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

**1.11 Please confirm that the trial protocol and owner consent form (including safety information for the owner) have been submitted with this application form:**

**Yes:**

**1.12 If the investigational or control product has a Marketing Authorisation[[4]](#footnote-4) in the UK, another EU or EEA country, or a third country (USA, Canada, Japan, New Zealand and Australia only), please provide the following details:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product name / designation** | **Country where authorised** | **MA no.** **(Vm no. in UK)** | **Species** | **Dosage / Route** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |  |

* If the product is authorised in an EU, EEA, or a third country and does not have a UK marketing authorisation (MA) please attach a copy of the MA and the product SPC (in English translation).
* Type A applications only: please highlight the EU or EEA authorised product being used during this study.

**SECTION 2 – TRIAL DETAILS**

**2.1** **Nature and purpose of the clinical trial (objectives):**

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

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

**2.4 Test Product:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product name / designation** | **Pharmaceutical form** | **Method of administration** | **Dose rate** | **Duration of administration** |
|  |  |  |  |  |

**2.5 Control (positive or negative / placebo) product(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product name / designation** | **Pharmaceutical form** | **Method of administration** | **Dose rate** | **Duration of administration** |
|  |  |  |  |  |

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

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

**2.7** **Estimated duration of trial:**

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

1. Inclusion criteria:
2. Exclusion criteria:

**2.9 Criteria for withdrawal of animals from the trial:**

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

**2.11 Name and qualifications (including RCVS registration number) of the Investigator(s)[[5]](#footnote-5):**

**2.12 Details of the test site(s)[[6]](#footnote-6), including the name of the Investigator with responsibility at each individual test site:**

**2.13 Name and qualifications (including RCVS registration number) of the overall trial Monitor:**

**2.14 Name and qualifications of the individual with responsibility for pharmacovigilance:**

**2.15 If any trial procedures are authorised and regulated in accordance with the Animals (Scientific Procedures) Act 1986, as amended, these should be identified and the Home Office Project License number should be provided:**

**SECTION 3 – CHEMISTRY AND MANUFACTURING INFORMATION**

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

**Yes (go to 3.3):**       **No (go to 3.2):**

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

**Yes (go to 3.3):**       **No (go to 3.4):**

**3.3** **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 (Yes/No)?**

**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:       ***Further information is NOT required unless a placebo product is to be used.*** *If this is the case, please complete section 3.4, 3.5 and 3.8 for the placebo product only*.

**If no,** please indicate deviations from MA:

In addition, please provide supporting data for the product under relevant headings below (section 3.4 – 3.9). ***If a*** ***placebo product is to be used,*** *please also complete section 3.4, 3.5 and 3.8 for the placebo product*.

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

|  |  |  |
| --- | --- | --- |
|  **Ingredients** | **Unit Composition** | **Grade/Specification \*** |
| **Active Substance(s)** |
|  |  |  |
|  |  |  |
| **Other Substance(s)** |
|  |  |  |
|  |  |  |
|  |  |  |
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 \* i.e. Ph. Eur./BP or in-house specification

 **Please list any materials removed during manufacture:**

**3.5 Pack Details:**

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

**3.6 Manufacture of Finished Product:**

1. Finished product manufacturer’s name and address:

1. Assembler’s (packaging and labelling) name and address:

1. Brief details of finished product manufacture, including in-process controls:

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

1. Active substance manufacturer’s name and address:

1. 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** |
|  |  |  |
|  |  |  |
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1. If non-pharmacopoeial, provide information on potential impurities and their significance in terms of safety.

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

1. Please provide specifications for non-pharmacopoeial excipients (as listed in 3.4):

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

1. Please provide a declaration of compliance with TSE regulations:

**3.8 Finished Product Release Specification:**

|  |  |  |
| --- | --- | --- |
| **Test** | **Limit** | **Test Method** |
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* 1. **Stability and Shelf Life:**

i Proposed shelf life and storage conditions:

1. Proposed in-use shelf life (if appropriate):

1. Please provide supporting stability data to support the above:

**SECTION 4 – HUMAN SAFETY INFORMATION (USER AND CONSUMER)**

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

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

**Yes:**       **No (go to 4.2):**

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

**4.2 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 4.3):**

**4.3 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 4.4):**

**4.4 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 4.5):**

**4.5 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):**

**4.6 Provide details of disposal or fate of 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 (Discussion should include the type of user (e.g. animal owner in the home), exposure, potential toxicity and information for users including warnings and suitable risk mitigation measures if necessary). |  |
|  |  |  |
| 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 the trial or, if contraindicated for use in animals intended for human consumption, one of the following statements:* For all food producing species except horses: ‘*Not to be used in animals for human consumption*’
* For horses, if the active substance is on the Essential Substances list, include the wording ‘*Not authorised in horses intended for human consumption’*, otherwise include the wording ‘*Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation*.’
 |  |

**SECTION 5 – 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 non-food animals.

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

Please provide an environmental risk assessment (ERA) 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 -

**ERA included (File name):**

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

**5.2 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):**

**5.3 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):**

**5.4 Disposal advice for unused product and empty containers, usually ‘Any unused product and containers should be returned to the trial sponsor’:**

**SECTION 6 – TARGET SPECIES SAFETY**

Please provide data supporting target species safety. The VMD will need to be sure that safety in the target species is acceptable at the proposed dosage and for the proposed duration of administration, and that there is a reasonable margin of safety. A critical summary of the data submitted in support of target species safety should be provided.

For Type A applications it may not be necessary to provide target species safety data where an existing UK, EU or EEA authorisation is for:

* the same target species,
* the same route of administration, and
* the dose proposed for the trial is the same or lower than the authorised dose.

HOWEVER, if based on the particular characteristics of the study population, the risks associated with administration of the test product cannot be extrapolated from the existing marketing authorisation (e.g. due to the reproductive status of study animals) then appropriate target species safety data should be submitted.

Data supporting target species safety:

**SECTION 7 – EFFICACY INFORMATION**

For ALL applications, please provide evidence that supports a reasonable expectation of efficacy (i.e. that the test product will produce the desired effect when used in accordance with the trial protocol). For example, reference to laboratory and/or pilot studies may be necessary. A critical summary of the data submitted in support of efficacy should be provided.

Data supporting efficacy:

|  |
| --- |
| **SECTION 8 – Declaration by the ATC Holder**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 inBLOCK 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. For studies conducted in accordance with GCP‑v the ATC holder is usually the Sponsor, or a person or organisation to whom the Sponsor has legally delegated this responsibility. [↑](#footnote-ref-1)
2. 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-2)
3. For example, a case where an existing ATC requires a change to its terms that cannot be authorised by way of an ATC variation application and a new ATC application is required. [↑](#footnote-ref-3)
4. If a product has a marketing authorisation (MA) in multiple countries, details of only one MA are required using the following order of preference: UK > EU/EEA > third country. By way of an exception, details of additional MAs should also be provided if they are of particular relevance to this ATC application. [↑](#footnote-ref-4)
5. The Investigator is the individual responsible for all aspects of study conduct at a study site; see VICH Topic GL9 (GCP). If details are not available at the point of application, any additional Investigator details must be submitted for consideration once known by way of an ATC variation application. [↑](#footnote-ref-5)
6. 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 an ATC variation application must be submitted for consideration before the trial commences. [↑](#footnote-ref-6)