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|  |  | **Veterinary Medicines Directorate**Woodham Lane, New HawAddlestone, SurreyKT15 3LSUnited KingdomTel: +44 (0)1932 336911Search for VMD on GOV.UK |

**APPLICATION FOR AN ANIMAL TEST CERTIFICATE (TYPE A or B)****USING AN IMMUNOLOGICAL / BIOLOGICAL 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:

Email Address:

Telephone No:

**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 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:**

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

* please highlight the Member State product being used as the basis for the UK ATC
* please attached a copy of the marketing authorisation and SPC for the product (in English)

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

**Yes:**       **No:**

**2.7 If any 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** **Pharmaceutical Form:**

**3.3** **Target Species:**

**3.4** **Indications:**

**3.5** **Estimated duration of trial:**

**3.6 Maximum no. of animals** (if exact numbers are not known, an estimated maximum number should be provided with confirmation of the exact numbers 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):

1. Treated (with the test product):
2. Positive controls:
3. Negative controls:
4. Placebo treated controls:

**3.7 Description of:**

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 Method of administration / dose rate/ duration of administration:**

1. Treated (with the test product):
2. Positive controls:
3. Negative controls:
4. Placebo treated controls:

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

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

**3.12 Details of test site(s) indicating the identity of the named Investigator with responsibility at each individual test site where multiple sites are named:** (if not known, an estimated maximum number should be provided with confirmation of the exact number of sites 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):

**3.13 Details of site investigator, if known (see VICH guideline on Good Clinical Practices for definition of investigator):**

**3.14 Please confirm that an example owner consent form has been provided:**

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

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

**3.17 For products containing GMOs, please provide evidence that a part B release consent notification has been granted (or applied for) by the GM Policy Unit:**

**3.18 Name and address of manufacturer:**

Name:

Address:

**3.19 Name and address of assembler:**

Name:

Address:

**3.20 Name and address of manufacturer of active substance(s):**

Name:

Address:

**SECTION 4 – ANALYTICAL INFORMATION**

* **For Type A applications – complete sections 4.1 to 4.4**
* **For Type B applications – completed ALL sections**

**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 4.8 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 Please provide batch release documentation, unless the batch has already been released by the VMD, or other competent authority in another member state:**

Please tick appropriate box:

**Batch release documentation provided:**     , or

**Batch release certificate provided:**      , or

**Batch release certificate to be provided before trial starts:**

**4.6 Please provide justification for any changes in the posology (formulation, manufacture and specification):**

**4.7 If applicable, please provide details for the placebo (formulation, manufacture and specification):**

**4.8 Please confirm that you have provided a table of qualitative and quantitative particulars:**

**4.9 Please provide the following:**

1. Details of containers and closures

1. Description of stages of manufacture and flow charts

1. Table of blending details

1. Starting materials listed in the Pharmacopoeia

1. Starting materials not listed in the Pharmacopoeia (biological origin, non-biological origin, media)

1. Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

1. In process control tests

1. Final product specifications, where appropriate

1. Stability data, if appropriate

1. For products containing GMOs, requirements listed in Annex II, Directive 2001/18

**SECTION 5 – SAFETY INFORMATION**

This section applies to Type B applications only.

**5.1 Please provide the following:**

1. Safety in the target species

1. Study of residues

1. Spread of the vaccine strain (for live vaccines)

1. Dissemination in the vaccinated animal (for live vaccines)

1. Reversion to virulence (for live vaccines)

1. Ecotoxicity

Further data under Part III, Safety, may be required to satisfy the VMD that the proposed use of the product will not adversely affect the safety of the product to the treated or other animals, users and the environment.

**SECTION 6 – EFFICACY INFORMATION**

**6.1** 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.

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| **Section 7 – 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 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. 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)