

## IMMUNOLOGICAL APPLICATION FOR AN ANIMAL TEST CERTIFICATE

**N.B. The test must not start until your ATC has been issued.**

**The test must be carried out in accordance with the terms and conditions on which the ATC has been granted**

Please complete this form in BLOCK LETTERS and refer to VMG Note 8 or guidance in completing it.

Four copies of the completed form and supporting data should be submitted to the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS. Wherever possible, the application should also be supplied in a suitable electronic form.

For Licensing Authority Use	
Appl No.	
VMP No.	
Application Type: A or B	
Date Acknowledged	
Fee	£
Signature	
Date	

**1. STANDARD PARTICULARS:** (complete shaded boxes for Type A and B applications)

Name of Product:			
Name and address of applicant		Name and address of proposed ATC holder if different	
Telephone No:		Telephone No:	
Fax No:		Fax No:	
e-mail:		e-mail:	
Applicant's reference no.			
Application Type, A or B			

All the following information relevant to the proposed trial should be included in a single bound volume, indexed with pages numbered consecutively. It is expected that the applicant complete the following details, cross referring to the document if necessary.

**2. ADMINISTRATIVE DATA FOR COMPLETION FOR TYPE A AND B APPLICATIONS:**

2.1 Earlier ATC/ATX Authorisation no. Name if different	Yes/No
2.2 Details of any UK Marketing Authorisations (Same Formulation)	Vm...../.....

2.3 Details of any other EU Marketing Authorisations				
Member State	MA No.	Species	Dosage/Route	Withdrawal period if applicable
<i>Highlight the Member State being used as the basis for the UK ATC submission (Type A ATCs).  <b>Attach Member State MA and SPC (both original and English translation)</b></i>			<i>Provide and indicate location of document</i>	
<b>2.4 Proposed label and any package inserts (test article and placebo):</b>			<i>Provide and indicate location of document</i>	

### 3. Trial Details (complete for Type A and Type B applications)

3.1	Nature and purpose of the test (objective):	
3.2	Pharmaceutical form:	
3.3	Target species:	
3.4	Indications	
3.5	Estimated duration of trial:	
3.6	Maximum no. of animals  i. Treated (with the test product)  ii. Positive controls  iii. Negative controls  iv. Placebo treated controls	
3.7	Description of:  i. Inclusion criteria  ii. Exclusion criteria	<i>Provide and indicate location of document</i>
3.8	Description of safety monitoring (provision for monitoring, investigating and reporting suspected adverse reactions, details of clinical assessments, blood tests etc.)	<i>Provide and indicate location of document</i>

3.9	For products containing GMOs, evidence that a part B release consent notification has been granted or applied for by the GM Policy unit (type A ATC)	
3.10	Method of administration/dose rate and interval/duration of administration  i. Treated (with the test product)  ii. Positive controls  iii. Negative controls  iv. Placebo treated controls	
3.11	Name and qualifications of the overall test Monitor	
3.12	Details of test site	
3.13	Details of site supervisors	
3.14	Disposal of unused product	
3.15	Disposal or fate of test food producing animals ( <i>not intended to enter the human food chain for food</i> )	
3.16	Manufacturer's name and address	
3.17	Assembler's name and address	
3.18	Name and address of manufacturer of active substance(s)	

#### 4. ANALYTICAL INFORMATION:

**Type A applications complete sections 4.1 – 4.4**

**Type B applications all sections apply :**

4.1	A signed statement confirming that the product to be trialled is identical in all respects (e.g. strength, formulation, pack, manufacture, control) to that specified in the Marketing Authorisation	
4.2	Batch release documentation, unless the batch has already been released by the VMD or a batch release certificate is available from another EU Member State	
4.3	Justification for any changes in the posology and method of administration	
4.4	If relevant, details for the placebo (formulation, manufacture and specification)	
4.5	Table of qualitative and quantitative particulars	
4.6	Containers and closures	
4.7	Description of stages of manufacture and flow charts	
4.8	Table of blending details	
4.9	Starting materials listed in Pharmacopoeia	
4.10	Starting materials not listed in Pharmacopoeia (biological origin, non-biological origin, media)	
4.11	Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies	
4.12	In process control tests	
4.13	Final product specifications where appropriate	
4.14	Stability if appropriate	
4.15	For products containing GMOs, requirements as listed on Annex II, Directive 2001/18	

**5. SAFETY:** (for completion for Type B applications)

5.1	Safety in the target species	
5.2	Study of residues	
5.3	Spread of the vaccine strain (for live vaccines)	
5.4	Dissemination in the vaccinated animal (for live vaccines)	
5.5	Reversion to virulence (for live vaccines)	
5.6	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.

**6. EFFICACY INFORMATION:**

Efficacy data are not usually required. However, if brief details of pilot studies etc. are submitted as evidence that there is a reasonable expectation that the test product will produce the desired effect, please index the documents.

## 7. DECLARATION

### DECLARATION

I/We apply for an ATC, and undertake to abide by the terms and conditions of any ATC issued in response to this application. I/We also undertake to inform the Licensing Authority forthwith of:

- a. any matter coming to our attention which might affect the safety in use of the product;
- b. the discontinuation of the test with an explanation.

**Signature** of the Applicant – person responsible for the content of the application (see paragraph 24)

.....

Date

...../...../.....

Name in BLOCK LETTERS

.....

Status

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