

# PHARMACEUTICAL APPLICATION FOR A TYPE “S” 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 for guidance in completing it. You should ensure that your trial is eligible for a Type S ATC, otherwise complete the application form for Types A and B.

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	
App No.	
VMP No.	
Date Acknowledged	
Fee	£
Signature	
Date	

## 1. STANDARD PARTICULARS: (complete shaded boxes)

Name of Investigational 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.			

**All the following information relevant to the proposed trial should be included either on the application form or in one or more bound volumes, indexed with pages numbered consecutively. It is expected that the applicant complete the following details, cross referring to the documentation if necessary.**

## 2. ADMINISTRATIVE DATA

2.1 Earlier ATC Authorisation no. Name if different		Yes/No		
2.2 Details of any UK Marketing Authorisations/ Product Licences (Same Formulation) for investigational product and control product <sup>1</sup>		Marketing Authorisation/Product Licence Number:		
2.3 Details of any EU Marketing Authorisations/Product Licences for investigational and control product				
Member State	MA No	Species	Dosage/Route	Withdrawal period if applicable
<b>Attach Member State SPC (both original and English translation)<sup>2</sup></b>			<i>Provide and indicate location of document</i>	
2.4 Details of Marketing Authorisations/ Product Licences in third countries (United States of America, Canada, Japan, New Zealand and Australia only) for investigational and control product				
Country	MA/product licence no. or equivalent	Species	Dosage/Route	Withdrawal period if applicable
<b>Attach SPC or equivalent e.g. data sheet (both original and English translation)<sup>3</sup></b>			<i>Provide and indicate location of document</i>	
2.5 For products to be imported into the UK, please provide the following information:				
Name and address of manufacturer or Marketing Authorisation/Product Licence holder				
Name and address of authorised importing Wholesale Dealer				
Country from where the import is to be made				

<sup>1</sup> Insert the product name and marketing authorisation (Vm) number or product licence number (PL). Vm numbers are used for veterinary authorised products and PL numbers for human authorised products.

<sup>2</sup> The SPC is the Summary of Product Characteristics. This information should be available from the Marketing Authorisation Holder, the relevant national regulatory agency, or, for some products at [www.eudrapharm.eu](http://www.eudrapharm.eu)

<sup>3</sup> This information should be available from the Marketing Authorisation Holder or the relevant national regulatory agency.

### 3. TRIAL DETAILS

3.1.	Nature and purpose of the trial (give a brief outline of the aims and objectives and justification for the trial)	
3.2	Target species (only one species per trial)	
3.3	Proposed indications for the product:	
3.4	Estimated duration of trial	
3.5	Maximum no. of animals:  i. Treated (with the investigational product) <sup>4</sup>  ii. Positive controls  iii. Negative/placebo controls	
3.6	Description of  i. Inclusion criteria  ii. Exclusion criteria	
3.7	Who will administer the product to the animal (investigator, owner, other)?	

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<sup>4</sup> Not more than 50 animals should be enrolled to the test product group, unless a clear justification in terms of statistical aspects of the study design is given.

3.8	<p>Method of administration, dose rate and duration of administration</p> <p>i. Treated (with the investigational product)</p> <p>ii. Positive controls</p> <p>iii. Negative/placebo controls</p>	
3.9	<p>Procedure used in preparation of the product prior to administration and to achieve accuracy of dosing (where relevant)<sup>5</sup></p>	<i>Provide and indicate location of document</i>
3.10	<p>Details of user safety warnings to be used for labelling, package leaflets, owner information sheets etc. (refer to Annex 1 for guidance)</p>	<i>Provide and indicate location of document</i>
3.11	<p>Statement of target species safety warnings to be used for labelling, package leaflets, owner information sheets etc. if required (refer to Annex 1 for guidance)</p>	
3.12	<p>Description of safety monitoring (Provision for monitoring, investigating and reporting suspected adverse reactions, details of clinical assessments, blood test etc. Provision of 24h care where animals are outside the test site. Provision of rescue treatment for animals administered placebos.)</p>	<i>Provide and indicate location of document</i>
3.13	<p>Name and qualifications of the overall test Monitor or Senior investigator (see VICH guideline on Good Clinical Practices for definition of Monitor)</p>	

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<sup>5</sup> For example, advise on:

- specialist equipment to be used for preparation of chemotherapy drugs
- safeguards for the administrator
- divisibility of tablets to achieve the correct dose

Products should not be altered in such a way as to change the pharmaceutical form, or by dilution etc except as advised in the SPC.

3.14	Details of investigator(s) Names and professional qualification of investigating veterinarians	
3.15	Details of test site(s) (addresses of veterinary premises of investigators)	
3.16	Name and qualifications of the person responsible for pharmacovigilance (i.e. reporting suspected adverse reactions to the VMD) <sup>6</sup>	
3.17	Please confirm that any waste product and empty containers will be disposed of in accordance with current regulations.	
3.18	Where relevant, provide confirmation that food species will not enter the food chain	
3.19	Disposal or fate of test food producing animals ( <i>not intended to enter the human food chain for food</i> )	<i>Provide and indicate location of document</i>
3.20	Authorised or statutory withdrawal periods for food producing species intended to enter the food chain <sup>7</sup>	<i>Provide and indicate location of document</i>

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<sup>6</sup> This person may be the Monitor or Senior investigator

<sup>7</sup> If there is no authorised withdrawal period for the target species, or the product is being administered using a higher dose regimen than that authorised, then withdrawal periods should be in accordance with those given in the Veterinary Medicines Regulations, Schedule 4. If the product is to be used for the treatment of horses, and the active substance is listed as “essential for the treatment of equidae” according to regulation (EC) 1950/2006, a 6-month withdrawal period should be applied.

#### 4. TARGET SPECIES SAFETY:

- Provide the information indicated below for all applications except where an existing EU authorisation is for the same species and the same dosing regimen

Published literature references to provide supportive evidence for safety in the proposed species, using at least the proposed dose regimen (refer to Annex A of VMGN 8 for further detail)	<i>Provide and indicate location of documents</i>
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#### 5. EFFICACY INFORMATION:

- For all applications, provide evidence that there is a reasonable expectation that the test product will produce the desired effect in the same species using the proposed dosage regimen

Published literature references (refer Annex A of VMGN 8 for further detail)	<i>Provide and indicate location of documents</i>
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#### 6. DECLARATION

<p>DECLARATION</p> <p>The study protocol has been reviewed by the senior investigator and at least two other veterinary surgeons who are independent of the trial, and in our opinion, it is ethical and is to be conducted in accordance with the RCVS Guide to Professional Conduct and “recognised veterinary practice”.</p>
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Signature of the Senior investigator ..... Date ...../...../.....	Name in BLOCK LETTERS  
Signature of two other veterinary surgeons who have reviewed the protocol, as above, and are independent of the trial  ..... Date ...../...../.....  ..... Date ...../...../.....	Names (in BLOCK LETTERS) and qualifications <sup>8</sup>  
<ul style="list-style-type: none"> <li>▪ Informed owner consent will be obtained for any off-label or unauthorised use of the product</li> <li>▪ All suspected adverse reactions (including lack of efficacy) will be reported to the Suspected Adverse Reactions Surveillance Scheme (SARSS) at the VMD and all serious suspected adverse reactions (i.e. involving a human or which have caused increased mortality or serious ill health in treated animals) must be reported within 15 days.</li> </ul> <p>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:</p> <ol style="list-style-type: none"> <li>a. any matter coming to our attention which might affect the safety in use of the product;</li> <li>b. the discontinuation of the test with an explanation.</li> </ol>	
<b>Signature</b> of the Applicant – person responsible for the content of the application ..... Date ...../...../.....	Name in BLOCK LETTERS ..... Status .....

<sup>8</sup> Refer to paragraph 52 of VMGN 8. These veterinary surgeons should have a further qualification in the discipline concerned.

## Annex 1

### **Guidance on user and target species safety warnings to be used for labelling, package leaflets, owner information sheets etc.**

Please refer to paragraphs 57 & 58 of VMGN 8.

For trials conducted under a Type S ATC, it is the responsibility of the trial sponsor to ensure that the labelling/package leaflets conform to the requirements laid out in the VMGN. The investigating veterinary surgeon is also responsible for ensuring that products are labelled in accordance with Schedule 3, paragraph 13(2) of the Veterinary Medicines Regulations, with the exception that the name of the product may be omitted for the purposes of “blinding” the trial.

For the following products, no further information is required in the application form:

- EU (incl. UK) authorised veterinary medicinal products for which the labels and product literature are in English
- Products which are to be administered directly by the investigator, if there is no subsequent risk to other persons and adverse effects are not likely to occur after the animal has left the investigator’s direct supervision.

For all other products, a statement of user and target species warnings to be included in the product literature/labels should be given. Examples are given below:

#### **Target species safety warnings**

These should be divided into:

- contraindications (circumstances under which use of the product may have serious consequences for target species safety, and therefore the product should NOT be used), and
- special precautions for use in the target species (warnings to ensure safe use of the product in animals).

These warnings may relate to:

- particular routes of administration,
- concomitant disease conditions, e.g. renal, cardiac or hepatic failure
- age or weight (a minimum age, or weight based on accuracy of dosing, may need to be given)
- warnings not to use during pregnancy or lactation if there are inadequate reproductive safety data
- interactions with other drugs
- sensitive sub-populations (e.g. related to breeds such as collies)
- known adverse effects

#### **User safety warnings**

User safety warnings are the precautions and special instructions for handling and administering the product. These warnings should:

- (i) give precautions to take when handling the product, e.g. avoid accidental contact with eyes.

(ii) give advice on what to do in the event of accidental occurrence. e.g in case of accidental contact with eyes, wash immediately with plenty of water. If irritation persists seek medical advice.

What user warnings to use and where to find the information:

- If the product you are using is a veterinary medicine:  
Use the precautions and warnings on the label or given in the package leaflet; if the product is from outside the EU and/or the labels or package leaflet are not in English, you should get these translated to provide the information.
- If the product is a human medicine:  
Refer to the label and package leaflet for guidance and any information that is specifically related to the handling of the product and precautions to take; it should be noted that warnings relating to effects to humans from “taking” the product are not usually relevant to "handling" and are not required on the labels of ATCs. If you are unsure, you should seek advice from VMD. If the product is from outside the EU and/or the labels or package leaflet are not in English, you should get these translated to provide the information.
- If there is no information available:  
Seek advice from the VMD on the user warnings that will be required.