

CLIENT CONFIDENTIAL

Study enquiry – Veterinary Research Management Ltd

Please provide as much information as possible to enable us to rapidly provide you with an accurate response and if appropriate a quotation. If some information is not known at this time or is estimated please indicate this.

Please note that by completing and sending this Study Enquiry Form, you agree to the information you have supplied being circulated by VRM to our affiliates, for the purposes of obtaining quotations from suitably qualified and equipped affiliate companies.

Name and address of the person to whom the quotation should be addressed	
Title of Study/ Objective	
Sponsor reference number if applicable	
Type of Study	<i>For example dose selection / dose confirmation / residue / TAS etc.</i>
Study Design	<i>For example two-period cross over with 7 day wash-out</i>
Standard - GLP/GCPv	
Guideline/s compliance	<i>List all relevant guidelines to be followed</i>
Protocol drafting	<i>Is a protocol already available? If not, does the sponsor wish to draft their own or have the test facility draft one?</i>
Approx duration of study to issue of draft report	
Duration of in-life phase	<i>Number of hours / days/ weeks excluding acclimatisation</i>
Species and any special requirements	<i>Ensure any special requirements (age, breed, pregnancy status, size/weight, disease status etc) are noted</i>
Total number of Animals	
Groups	<i>Number of groups and number of animals per group</i>
If appropriate challenge material required and who will provide it	<i>For example, Fasciola hepatica metacercariae to be provided by the test facility</i>
Route of Administration Dose to be administered	

Acclimatisation	<i>Number of days and any other specific requirements</i>
Parameters to be Monitored and frequency	<i>For example body weight weekly, clinical observations of X, Y and Z daily, body temperature etc.</i>
Veterinary Clinical examinations required pre- and post- TA administration	<i>Number and approximate timing of observations for each treatment group. For example all animals to receive a veterinary examination prior to enrolment and all treatment groups to be examined at days 1 and 30 post-TA administration.</i>
Veterinary Examination details	<i>Specify parameters to be recorded, for example gut motility, thoracic auscultation.etc.</i>
Time from last treatment to end of in-life phase of study	
Necropsy	<i>Indicate if required, and if so, list any specific observations to be recorded. Is histopathology also required?</i>
Sample analysis required & standard to which it is to be conducted (GLP / GCP)	<i>For example routine haematology on daily blood samples, urinalysis, residues, pK etc. Including number of sampling per study animal and the analytes required</i>
Statistics	<i>Are statistics required? If yes, who is to be responsible for their conduct – sponsor or test facility? Standard required. Any other pertinent details.</i>
Reporting	<i>If to GCPv, does the Sponsor wish to draft the study report or have the test facility do it (the Study director will per the regulations write all GLP reports). Any timing requirements for example for delivery of a first draft. Any other special requirements, for example a sponsor report template to be used.</i>
Archiving	<i>Do you wish the test site to archive copies or original data and for how long? Any other archiving requirements?</i>
Scheduling	<i>When will the test materials and protocol be available on site to start the study? When does the sponsor need the results and if different when is the signed off report required?</i>

Table 1 Treatment groups (delete as appropriate)

Group	Treatment	No of Animals	Dose rate (mg/kg)	Dose volume	Treatment Frequency or timing	Treatment duration	Total number of doses to be administered / animal
1	<i>Placebo</i>			<i>X ml/ 100kg</i>	<i>Every X hrs / daily</i>	<i>Y days</i>	
2	<i>TAP</i>			<i>X ml/ 100kg</i>		<i>Y days</i>	
3	<i>TAP</i>			<i>X ml/ 100kg</i>		<i>Y days</i>	
4	<i>TAP</i>			<i>X ml/ 100kg</i>		<i>Y days</i>	

Any other details: