



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

VETERINARY MEDICINES DIRECTORATE

For VMD use.
AN: SAM

Manufacturers Application Form For Products covered under Schedule 6 of the Veterinary Medicines Regulations (2009) (Exemption Scheme for Pet Animal Medicines)

PLEASE COMPLETE ALL RELEVANT SECTIONS IN THIS FORM
TYPED OR IN BLOCK CAPITALS LEGIBLY, USING BLACK INK

1. APPLICATION FORM: ADMINISTRATIVE DATA

1.1 Applicant's Details

If you are applying for a variation to your licence
please tick this box and only complete section 1
and those sections that require a change.

Company Name:	<input type="text"/>		
Licence No. (if known)	<input type="text"/>		
Trading Style(s):	<input type="text"/>		
Applicant's Name:	<input type="text"/>		
Address:	<input type="text"/>		
Postcode:	<input type="text"/>	Telephone:	<input type="text"/>
Mobile:	<input type="text"/>	Fax:	<input type="text"/>
E-mail:	<input type="text"/>		

Are you applying on behalf of the Proposed Authorisation Holder?
(e.g. if you are a consultant/representative)

Yes No

If YES, please fill out section 1.2

1.2 Contact Details for Communication (if different from above)

Contact Name:	<input type="text"/>		
Company Name:	<input type="text"/>		
Address:	<input type="text"/>		
Postcode:	<input type="text"/>	Telephone:	<input type="text"/>
Mobile:	<input type="text"/>	Fax:	<input type="text"/>
E-mail:	<input type="text"/>		

1.3 Invoicing Address Details (if different from Authorisation Holder Address)

Contact Name:

Company Name:

Address:

Postcode: Telephone:

Mobile: Fax:

E-mail:

2. SITE INFORMATION

2.1 Site Details

You will need to complete a copy of this section for each site that you wish to include on the Authorisation:

Site ID:

Site Name:

Address:

Postcode:

Contact Name:

Telephone: Fax:

Mobile:

E-mail:

2.2 Site Activities

Manufacture	<input type="checkbox"/>	Assembly and Packaging	<input type="checkbox"/>	Storage and Handling (picking of goods)	<input type="checkbox"/>
Distribution	<input type="checkbox"/>	Analytical Testing	<input type="checkbox"/>	Batch Release	<input type="checkbox"/>
*Import	<input type="checkbox"/>				

***Please Supply details of manufacturing site(s) from which importation occurs and GMP certification for site(s) if available:**

Manufacturing Operations – Site Functions

Please cross **MA** (*Manufacture and Assembly*) or **MO** (*Manufacture Only*) for each of the site functions proposed to be conducted:

<u>NON-STERILE PRODUCTS</u>	MA	MO
Unit and multi-dose liquids for internal use	<input type="checkbox"/>	<input type="checkbox"/>
Unit and multi-dose liquids for external use	<input type="checkbox"/>	<input type="checkbox"/>
Unit and multi-dose liquid aerosols (pressurised)	<input type="checkbox"/>	<input type="checkbox"/>
Semi-solid and other liquid non-sterile dosage forms	<input type="checkbox"/>	<input type="checkbox"/>

If **MA/MO** crossed please specify:

Solid unit-dose forms – tablets	<input type="checkbox"/>	<input type="checkbox"/>
Solid unit-dose forms – capsules, hard shell	<input type="checkbox"/>	<input type="checkbox"/>
Solid unit-dose forms – capsules, soft shell	<input type="checkbox"/>	<input type="checkbox"/>
Solid unit-dose forms – suppositories/pessaries	<input type="checkbox"/>	<input type="checkbox"/>
Solid multi-dose forms (including powders and granules)	<input type="checkbox"/>	<input type="checkbox"/>
Traditional Herbal Medicinal products	<input type="checkbox"/>	<input type="checkbox"/>
Other solid non-sterile dosage forms	<input type="checkbox"/>	<input type="checkbox"/>

ASSEMBLY OPERATIONS

Primary Packaging

Filling of primary containers	<input type="checkbox"/>	Yes
Liquid dosage forms	<input type="checkbox"/>	Yes
Semi-solid dosage forms (including creams and ointments)	<input type="checkbox"/>	Yes
Solid dosage forms (including tablets and powders)	<input type="checkbox"/>	Yes
Blister and/or strip packaging	<input type="checkbox"/>	Yes
Others	<input type="checkbox"/>	Yes

Secondary Packaging

Labelling of primary containers	<input type="checkbox"/>	Yes
Secondary packaging of primary containers	<input type="checkbox"/>	Yes
Packaging for parallel importation	<input type="checkbox"/>	Yes

OTHER OPERATIONS

LETTING AND/OR ACCEPTING CONTRACTS

- Applicants intends to be contract acceptor
(i.e. manufactures partially/wholly for others) Yes
- Applicants intends to be contract giver
(i.e. uses external manufacturers for some products) Yes
- Applicant intends to be contract acceptor
(i.e. carries out testing partially/wholly for others) Yes
- Applicants intends to be contract giver
(i.e. uses external test houses for some/all testing) Yes

Please give contact details of contract manufacturers and analysis providers and enclose copies of manufacturers licence / GMP certificate, if available:

OTHER INFORMATION

The following information is required for inspectorate action but will not appear on your authorisation:

- Are products of Animal/Human Origin (AHO) present at this site? Yes
- Do you supply stock which requires refrigeration or low temperature storage? Yes
- Are premises sound and secure and ready for inspection? Yes
- Are you conversant with Volume 4 – Medicinal Products for Human & Veterinary Use: Good Manufacturing Practice? Yes
- Are signed technical agreements available for inspection where applicable? Yes
- Do you import intermediate products for further processing? Yes

Please list the ingredients and pharmaceutical form to be manufactured under this authorisation, with trade names where known:

Active/Relevant Ingredient Name	Pharmaceutical Form	Trade Name

ANALYTICAL TESTING ACTIVITIES

Analytical Testing Activities at this Site

- Chemical/physical Yes No
- Microbiological/Environmental/LAL Yes No
- Others Yes No
- Is this lab involved in doing finished products testing? Yes No
- Is this lab involved in microbiological testing of finished products and/or raw materials? Yes No

SUPPLEMENTARY TESTING INFORMATION AT THIS SITE

- Stability testing Yes No

2.3 Further information which should be attached

- Have you submitted a Site Master File with your initial application? Yes No
- If NO, will a Site Master File be available on site during an inspection? Yes No

3. NAMED PERSONS

Please indicate below how many of the following types of personnel you have working at this site:

Personnel	Number
1. Qualified Person (QP)	
2. Production Manager/Supervisor (PM)	
3. Person responsible for Quality Control (QC)	
4. Total no. of personnel involved in the manufacturing process, e.g. Production, QC, QA, Maintenance etc.	

For each and every personnel type listed in boxes 1-3, please complete one of the appropriate following sections:

3.1 Qualified Person

All applications by a QP must include a relevant CV and each QP nomination must be signed by both the nominee and the applicant. **The QP should not be the same person as is responsible for production.** Please complete a separate entry for each QP:

Title:	<input type="text"/>	Personnel ID:	<input type="text"/>
First name(s):	<input type="text"/>		
Last name:	<input type="text"/>		
Business Address:	<input type="text"/>		
Postcode:	<input type="text"/>	Telephone:	<input type="text"/>
Fax:	<input type="text"/>	Mobile:	<input type="text"/>
E-mail:	<input type="text"/>		

Please indicate your status:

Permanent Employee Consultant

If you are a consultant, please give details of your availability. How frequently will you visit?

Qualifications relevant to this authorisation:

Experience (brief details of employment and responsibilities) relevant to this authorisation:

Professional Association(s):

Please submit a copy of the nominee's certificate of eligibility from the RPSGB, IOB or RSC, if available.

I confirm that the above particulars are accurate and true to the best of my knowledge and belief.

I agree to be nominated as a Qualified Person.

Signed (Nominee): _____ Date: _____

Print Name: _____

Signed (Applicant): _____ Date: _____

Print Name: _____

3.2 Person Responsible for Production

Please complete a separate sheet for each person responsible for production.

In what capacity are you signing this? Please indicate in the box below:

Manager of Production Supervisor of Production

Title: Personnel ID:

First name(s):

Last name:

Business Address:

Postcode: Telephone:

Fax: Mobile:

E-mail:

Qualifications relevant to this authorisation:

Experience (brief details of employment and responsibilities) relevant to this authorisation:

Name and function of the person(s) to whom they report to (if applicable):

Area of responsibility

I confirm that the above particulars are accurate and true to the best of my knowledge and belief.

I agree to be nominated as the person responsible for production.

Signed (Nominee): _____ **Date:** _____

Print Name: _____

Signed (Applicant): _____ **Date:** _____

Print Name: _____

3.3 Person Responsible for Quality Control

Please give the following details of the person(s) with overall responsibility for quality control. **The person responsible for quality control should not be the same person as is responsible for production.** Where this responsibility is shared between more than one person, please complete a separate page for each person, and give details of each person's area of responsibility.

Title:	<input type="text"/>	Personnel ID:	<input type="text"/>
First name(s):	<input type="text"/>		
Last name:	<input type="text"/>		
Business Address:	<input type="text"/>		
Postcode:	<input type="text"/>	Telephone:	<input type="text"/>
Fax:	<input type="text"/>	Mobile:	<input type="text"/>
E-mail:	<input type="text"/>		

Qualifications relevant to this authorisation:

Experience (brief details of employment and responsibilities) relevant to this authorisation:

Name and function of the person(s) to whom they report to (if applicable):

Area of responsibility:

I confirm that the above particulars are accurate and true to the best of my knowledge and belief.

I agree to be nominated as the person responsible for Quality Control.

Signed (Nominee): _____ **Date:** _____

Print Name: _____

Signed (Applicant): _____ **Date:** _____

Print Name: _____

4. COMMENTS

Please provide any other information that may support your application.

You can also detail any changes to addresses, person names etc.

5. DECLARATION

I/We apply for the Grant of a Manufacturer's Authorisation for products exempted under Schedule 6 of the Veterinary Medicines Regulations (2009), to the proposed holder named in this application form and in respect of the activities to which the application refers.

5.1a The activities are to be only in accordance with the information set out in the application or furnished in connection with it.

5.2b To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed (Applicant): _____ **Date:** _____

Print Name: _____

State capacity in which signed: _____

Please send completed form to:
Licensing Services Section
Veterinary Medicines Directorate
Woodham Lane, New Haw
Addlestone
Surrey
KT15 3LS

We will acknowledge receipt of the application, please await the invoice before sending payment.