



Veterinary
Medicines
Directorate

VETERINARY MEDICINES DIRECTORATE
On behalf of the Secretary of State for the
Department for Environment, Food and Rural Affairs (Defra)

ISSUED BY:
MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
151 Buckingham Palace Road, London, SW1W 9SZ
T 020 3080 6000 www.gov.uk/mhra

Wholesale Dealer's Authorisation (WDA(V))

SECTION 1

1. The authorisation covers distribution by way of wholesale dealing of veterinary medicinal products by the authorisation holder named and storage of such products only on the premises specified.
2. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the veterinary medicinal products. If any change of premises is proposed prior approval must be sought from the Secretary of State. Any proposals to make structural alterations to the premises must also be notified to the Secretary of State. If the business should change hands, the company or person taking over the business will need to obtain their own authorisation, if they do not already have one, or vary and existing authorisation to include the additional site(s) before commencing wholesale dealing from these sites.
3. If an authorisation holder intends to import and hold unlicensed products into the UK, an application for a wholesale dealer's import certificate must be made. These products may only be released to a veterinary surgeon who holds a certificate from the Secretary of State entitling him to use the product.
4. This authorisation does not cover any manufacture and/or assembly process (e.g. packing, filling or labelling) of veterinary medicinal products including the import of authorised products from outside the EEA. If you wish to conduct any of these activities an application for a manufacturing authorisation must be made and an authorisation granted for that purpose.
5. The name and address of holders of WDAs for veterinary medicinal products together with the addresses of authorised sites are published on the MHRA website www.gov.uk/mhra.
6. An authorisation may be suspended if any fees are not paid in full as they fall due.
7. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.



SECTION 1 (continued)

8. Authorisation Structure

This authorisation is divided into three sections.

- (a) Section 1 (this section) identifies the authorisation holder and holds the authorising signature. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.
- (b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.
- (c) Section 3 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.
- (d) The authorisation holder is required to attach to his authorisation any replacement pages issued by the Secretary of State and to mark or destroy superseded pages as to render them invalid.



SECTION 1 (continued)

9. Authorisation Holder

- (a) WDA(V) Number: WDA(V) 8778 has been granted to –

AUTHORISATION HOLDER:	SIGMA PHARMACEUTICALS PLC
TRADING AS:	SIGMA PHARMACEUTICALS & FORTE DIRECT & ALMUS PHARMACEUTICALS
ADDRESS:	UNIT 1 COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM
CONTACT NAME:	DR BHARAT K H SHAH

- (b) This authorisation permits the holder to distribute by way of wholesale dealing, veterinary medicinal products of the description or general classification specified, to be stored at the named premises and using the named personnel in accordance with Section 3 of this authorisation.
- (c) This authorisation will continue to remain in force unless the holder does not deal in veterinary medicinal products for five years or the authorisation is suspended or revoked by the Secretary of State.
- (d) Date granted - 28/11/2017
- (e) Authorised by -

Name: Sean Kaiser

(A person authorised to approve on behalf of the Secretary of State for Defra)

Date: 28/11/2017



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SECTION 2

VARIATION HISTORY

This page will be amended if the authorisation is varied.

Date	Variation Detail
25/09/2006	Variation to create WDA due to change in legislation effective 14-08-06.
18/12/2009	Variation to add POM-VPS and NFA-VPS categories to site 91549.
04/03/2010	Variation to add Other sterile and non sterile products.
08/07/2011	Variation to change the trading style to Sigma Pharmaceuticals & Forte Direct & Almus Pharmaceuticals, add additional Admin/Procurement site; Forte Direct Limited, The Courtyard, 380 New Hythe Lane, Larkfield, Maidstone, Kent, ME20 6RZ, change the Communications address to; Hare Park Mills, Hare Park Lane, Liversedge, West Yorkshire, WF15 8EP and replace Mrs J Wright with Mr Bharat K H Shah as the Licence Holder Contact
12/08/2011	Internal variation to Site 91641: add Large volume sterile liquids, Semi-solid sterile dosage forms and Solid sterile dosage forms
28/11/2017	Internal update.



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SECTION 3 - SITE INFORMATION

The premises –

SITE NAME:	SIGMA PHARMACEUTICALS PLC
ADDRESS:	UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM
MHRA SITE NUMBER:	1689019

is named on WDA(V) number: WDA(V) 8778 the following are authorised at the named premises:

1. those operations as specified;
2. those descriptions of products or classes of product as specified;
3. the personnel named to carry out the roles as specified.

Any restrictions or clarifying remarks related to the scope of these Wholesaling operations:



SECTION 3 - SITE INFORMATION (continued)

USE OF PRODUCTS AT SITE	
<i>Administration to animals</i>	Yes

SITE TYPES	
<i>Distribution only</i>	No
<i>Storage and Handling (picking of goods)</i>	Yes
<i>Procurement/administration only (no storage)</i>	No

CATEGORIES OF PRODUCTS HANDLED AT THIS SITE	
<i>Prescription Only Medicines – Veterinary (POM-V)</i>	Yes
<i>Prescription Only Medicines – Veterinary, Pharmacy, Suitably Qualified Person (POM-VPS)</i>	Yes
<i>Non-Food Animal – Veterinary, Pharmacy, Suitably Qualified Person (NFA-VPS)</i>	Yes
<i>Authorised Veterinary Medicine - General Sales List (AVM-GSL)</i>	Yes
<i>Unlicensed veterinary medicinal products</i>	No
<i>Cold Chain Products</i>	No



SECTION 3 - SITE INFORMATION (continued)

SPECIFIC SITE ACTIVITIES	
<i>Parallel imported Veterinary Medicinal Products are imported at this site.</i>	Not Authorised
<i>Veterinary Medicinal Products requiring refrigeration or low temperature storage handled at this site</i>	Not Authorised



All pharmaceutical forms included within the specified categories of product.

SECTION 3 - SITE INFORMATION (continued)

Personnel

<u>Person Number</u>	<u>Name</u>	<u>Personnel Type</u>
		<u>WQP</u>
117336	Mr Bharat Shah	Yes

Key to Role:

WQP – Wholesale Dealers Qualified Person

