



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

UK Manufacturer

Part 1

Issued following an inspection in accordance Schedule 2 of the Veterinary Medicines Regulations 2013 as it has effect in Northern Ireland and Great Britain.

The competent authority of: UNITED KINGDOM (**Veterinary**) confirms the following:

The manufacturer: **Elanco UK AH Limited**

Site address: Elanco Speke Operations
Fleming Road
Speke
Liverpool
Merseyside
L24 9LN
United Kingdom

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA 50813** in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **13th July 2023**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice as required by the Veterinary Medicines Regulations 2013.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified on EudraGMP or on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Date: 26th September 2023

Name: CONFIDENTIAL

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
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Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	Sterile Products: 1.1.3 Batch certification
1.2	Non-sterile products: 1.2.2 Batch certification
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging: N/A
1.6	Quality Control testing: N/A

2. IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products N/A
2.2	Batch certification of imported medicinal products N/A
2.3	Other importation activities N/A

Any restrictions or clarifying remarks related to the scope of this certificate:

None

Name and signature of the authorised person of
the Competent Authority of the UK:

Signature: CONFIDENTIAL

Date: 26th September 2023

Name: CONFIDENTIAL