

Certificate No: VMDGMP/M178/2023

## **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:

Fleming Road Speke Liverpool Merseyside L24 9LN United Kingdom

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA 1345** in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **10<sup>th</sup> to 12<sup>th</sup> 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 GOV.UK If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Date: 20<sup>th</sup> September 2023

Name: CONFIDENTIAL



The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food and Rural Affairs

## Part 2

Veterinary Medicinal Products

1.	MANUFACTURING OPERATIONS
1.1	Sterile Products:
	N/A
1.2	Non-sterile products:
	<ul> <li>1.2.1.6 Liquids for internal use</li> <li>1.2.1.8 Other solid dosage forms</li> <li>1.2.1.16 Veterinary premixes</li> <li>1.2.2 Batch certification</li> </ul>
1.3	Biological medicinal products:
	N/A
1.4	Other products or manufacturing activity:
	N/A
1.5	Packaging:
	<ul><li>1.5.1.6 Liquids for internal use</li><li>1.5.1.8 Other solid dosage forms</li><li>1.5.1.16 Veterinary premixes</li><li>1.5.2 Secondary packaging</li></ul>
1.6	Quality Control testing:
	<ul><li>1.6.2 Microbiological: non-sterility</li><li>1.6.3 Chemical/Physical</li><li>1.6.4 Biological</li></ul>

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:

At the time of the last inspection and issue of this certificate, the site was operated by TriRx Speke Limited. However, ownership of the manufacturing premises has transferred to Elanco UK AH Limited. The premises, staff and operations covered by this certificate have been unchanged in the transfer

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

Signature: CONFIDENTIAL

Date: 20<sup>th</sup> September 2023

Name: CONFIDENTIAL