Veterinary Medicines Directorate

Certificate No: VMDGMP/M136/2022

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: **Boehringer Ingelheim Animal Health UK Limited.**

Site address: Biological Laboratory
Ash Road
Pirbright
Surrey
GU24 0NQ
United Kingdom

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **11819** in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27th September to 01st October 2021**, 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: 15 February 2022 Name: CONFIDENTIAL

Part 2

Veterinary Medicinal Products

1.	MANUFACTURING OPERATIONS
1.1	Sterile Products: 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids 1.1.3 Batch certification
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: 1.3.1.2 Immunological products 1.3.2.2 Batch certification of immunological products
1.4	Other products or manufacturing activity: 1.4.1.3 Other - biological active starting materials
1.5	Packaging only: 1.5.2 Secondary packaging
1.6	Quality Control testing: 1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/ Physical 1.6.4 Biological

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

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

Certificate updated to reflect activities on ManA

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

Signature: CONFIDENTIAL

Date: 15 February 2022

Name: CONFIDENTIAL