Veterinary Medicines Directorate

Certificate No: VMDGMP/M185/2023

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

Issued following an inspection in accordance with 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: **Zoetis LLC.**

Site address: **601 Cornhusker Highway**
Lincoln
Nebraska 68521
USA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the United Kingdom in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2nd to 6th May 2022**, 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: 6th December 2023

Name: CONFIDENTIAL

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
Search for VMD on GOV.UK

Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	Sterile Products: 1.1.1 Aseptically prepared 1.1.1.1 Large volume liquids 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: 1.3.1 Biological medicinal products 1.3.1.2 Immunological products
1.4	Other products or manufacturing activity: 1.4.1 Manufacture of: 1.4.1.3 Other – Biological active starting material Adjuvant for incorporation into veterinary vaccine 1.4.2 Sterilisation of active substances/excipients/finished products: 1.4.2.1 Filtration
1.5	Packaging: N/A
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

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

This certificate covers the manufacturing activities listed above in building 2 and specific areas of building 1 (Unit 62 formulation filling and lyophilisation, master seed facility, and pilot plant) along with associated activities at the Lincoln sites (e.g. QC testing and warehousing).

Certificate updated to include Unit 62 formulation, filling and lyophilisation following targeted inspection in September 2023.

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

CONFIDENTIAL

Signature: _____

Date: 6th December 2023

Name: CONFIDENTIAL