Veterinary Medicines Directorate

Certificate No: VMDGMP/M024/2018-rev2

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended.

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

The manufacturer: **Merck Animal Health (also known as Intervet Inc.)**

Site address: 29160 Intervet Lane
PO Box 318
Millsboro
Delaware
USA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 80(4) of Directive 2001/82/EC transposed in the following national legislation:

The Current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18th to 22nd June 2018**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

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 in EudraGMP. If it does not appear, please contact the issuing authority.

Signature: Confidential

Date: 15 December 2021

Name: Confidential

Veterinary Medicines Directorate
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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: 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: 1.3.1.2 Immunological products – sterile and low bioburden vaccines
1.4	Other products or manufacturing activity: 1.4.1.3 Active biological starting substances
1.5	Packaging: 1.5.2 Secondary packing
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

This certificate is limited:

- Production – buildings 3 & 14 (Building 14 only for crimp capping of low bioburden veterinary vaccines)
- Warehousing – buildings 4 & 14
- QC testing – buildings 1 & 15

Manufacturing processes covered by the scope of this certificate are production of viral antigens (via cell or egg systems) for use in the formulation of veterinary vaccines in house or in other Merck / MSD facilities. Production of filled packed vaccine (eg. Innovax-ILT) in the TCP fill area is also covered. In addition, the filling and freeze-drying of unlabelled vaccines in building 3 and capping in building 14 is also covered by this certificate.

Due to the Covid-19 pandemic a planned inspection of the site has been postponed. A risk assessment has been performed and following this, the validity of this GMP certificate has been extended to 31st December 2022

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

Signature: Confidential

Date: 15 December 2021

Name: Confidential

Veterinary Medicines Directorate
tel: Confidential
email: Confidential