Veterinary Medicines Directorate

Certificate No: VMDGMP/M171/2023

# 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: **MSD Animal Health UK Limited**

Site address:
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
UK

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA1708** in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27th February to 3rd March 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: 7th June 2023

Name: CONFIDENTIAL

**Part 2**

Veterinary Medicinal Products

| | |
|---|---|
| **1.** | **MANUFACTURING OPERATIONS** |
| 1.1 | Sterile Products:<br>1.1.1 Aseptically prepared (processing operations for the following dosage forms)<br>1.1.1.1 Large volume liquids<br>1.1.1.4 Small volume liquids<br><br>1.1.3 Batch certification |
| 1.2 | Non-sterile products:<br><br>1.2.1 Non-sterile products (processing for the following dosage forms)<br>1.2.1.6 Liquids for internal use<br><br>1.2.2 Batch certification |
| 1.3 | Biological medicinal products:<br><br>1.3.1.2 Immunological products |
| 1.4 | Other products or manufacturing activity:<br><br>1.4.1 Manufacture of:<br>1.4.1.3 Other - Biologically active starting materials<br>Manufacture and lyophilisation of biological seed material<br><br>1.4.2 Sterilisation of active substances/excipients/finished product:<br>1.4.2.1 Filtration<br>1.4.2.4 Chemical |
| 1.5 | Packaging:<br><br>1.5.1 Primary packing<br>1.5.1.6 Liquids for internal use<br><br>1.5.2 Secondary packing |
| 1.6 | Quality Control testing:<br>1.6.1 Microbiological: sterility<br>1.6.2 Microbiological: non sterility<br>1.6.3 Chemical/Physical<br>1.6.4 Biological |

| 2. | IMPORTATION OF MEDICINAL PRODUCTS |
|---|---|
| 2.1 | Quality control testing of imported medicinal products<br>2.1.1 Microbiological: sterility<br>2.1.2 Microbiological: non sterility<br>2.1.3 Chemical/Physical<br>2.1.4 Biological |
| 2.2 | Batch certification of imported medicinal products<br>2.2.1 Sterile products<br>2.2.1.1 Aseptically prepared<br>2.2.1.2 Terminally sterilised<br>2.2.2 Non sterile products<br>2.2.3 Biological medicinal products<br>2.2.3.2 Immunological products |
| 2.3 | Other importation activities<br>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: 7th June 2023

Name: CONFIDENTIAL