Veterinary Medicines Directorate

Certificate No: VMDGMP/M198/2024

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: **Norbrook Laboratories Limited**

Site address: Station Works
Camlough Road
Newry
County Down, NI
BT35 6JP

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA 2000** in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27th – 29th February 2024**, 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: 21 May 2024

Name: CONFIDENTIAL

Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	**Sterile Products:** 1.1.1 Aseptically Prepared 1.1.1.1 Large volume liquids 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids 1.1.1.5 Solids and implants 1.1.2 Terminally Sterilised 1.1.2.1 Large volume liquids 1.1.2.2 Semi-solids 1.1.2.3 Small volume liquids 1.1.2.4 Solids and implants 1.1.3 Batch Certification
1.2	**Non-sterile products:** 1.2.1 Non-sterile products 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.16 Veterinary premixes 1.2.2 Batch Certification
1.3	**Biological medicinal products:** N/A
1.4	**Other products or processing activity:** 1.4.2 Sterilisation of active substances/excipients/finished product: 1.4.2.1 Filtration 1.4.2.2 Dry heat 1.4.2.3 Moist heat
1.5	**Packaging** 1.5.1 Primary packing 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.16 Veterinary premixes 1.5.2 Secondary packing
1.6	**Quality Control testing:** 1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

2.	IMPORTATION OF MEDICINAL PRODUCTS
2.1	**Quality control testing of imported medicinal products** 2.1.1 Microbiological: sterility 2.1.2 Microbiological: non sterility 2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products** 2.2.2 Non-sterile products
2.3	**Other importation activities** N/A

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

Manufacture of Penicillin and Cephalosporins (B-lactams) is performed at the Norbrook Laboratories Limited Station Works site.

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

Signature: CONFIDENTIAL

Date: 21 May 2024

Name: CONFIDENTIAL