Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK ManA 50813 Insp GMP 50813/16842-0018[V]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 5 of the current Veterinary Medicines Regulations

The competent authority of United Kingdom confirms the following :

The Manufacturer : ELANCO SPEKE OPERATIONS

Site address : ELANCO SPEKE OPERATIONS, FLEMING ROAD, SPEKE, LIVERPOOL, L24 9LN, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK ManA 50813 in accordance with Regulation 5 of The current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/06/2018 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation 5 of the current Veterinary Medicines Regulations

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.16] Veterinary premixes

[1.2.2] Batch certification

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Manufacturing of pegbovigrastim (PEG-bGCSF) API and importation of pegbovigrastim (PEG-bGCSF) gr pegbovigrastim (PEG-bGCSF) API.

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[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

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.2] Immunological products

[2.2.3.8] Other biological medicinal products

Vaccines

[2.3] Other Importation Activities

[2.3.4] Other

Manufacturing of pegbovigrastim (PEG-bGCSF) API and importation of pegbovigrastim (PEG-bGCSF) gr

21/05/2019	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential

MHRA-GMDP MHRA

Medicines and Healthcare products Regulatory Agency

Tel : Confidential

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