



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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: **Animax Ltd**

Site address: Shepherds Grove West
Stanton
Bury St Edmunds
Suffolk
IP31 2AR
United Kingdom

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA14016** in accordance with Art 44 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 **16-17th July 2019**, 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: 12 September 2019

Name: Confidential

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	Sterile Products: N/A
1.2	Non-sterile products: 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.8 Other solid dosage forms 1.2.1.15 Intraruminal devices 1.2.2 Batch certification
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging only: 1.5.1 Primary packaging 1.5.2 Secondary packaging
1.6	Quality Control testing: 1.6.3 Chemical/ physical

2. IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products N/A
2.2	Batch certification of imported medicinal products 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: 12 September 2019

Name: Confidential

Veterinary Medicines Directorate
tel: Confidential
email: Confidential