



## 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: **Argenta Dundee Limited**

Site address: Kinnoull Road  
Dunsinane Industrial Estate  
Dundee  
DD2 3XR

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA 17381** 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 **20<sup>th</sup> March 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: 21<sup>st</sup> March 2019

Name: Confidential

## Part 2

Veterinary Medicinal Products
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<b>1. MANUFACTURING OPERATIONS</b>	
1.1	Sterile Products: N/A
1.2	Non-sterile products: 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.2 Batch certification
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging: 1.5.1 Primary packing 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.2 Secondary packing
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

<b>2. IMPORTATION OF MEDICINAL PRODUCTS</b>	
2.1	Quality control testing of imported medicinal products N/A
2.2	Batch certification of imported medicinal products N/A
2.3	Other importation activities 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: 21<sup>st</sup> March 2019

Name: Confidential

Veterinary Medicines Directorate  
tel: Confidential  
email: Confidential