Veterinary Medicines Directorate

Certificate No: VMDGMP/M034/2016

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: **Hydrokem Aerosols Limited**

Site address: Hickmans Road
Birkenhead
Wirral
CH41 1JH

Has been inspected under the national inspection programme in connection with Manufacturing Authorisation no. **ManA1004** 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 August 2016**, 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: P. A. Brown

Date: 14th October 2016

Name: Penny Brown

Part 2

Veterinary Medicinal Products

1.	MANUFACTURING OPERATIONS
1.1	Sterile Products: Not applicable
1.2	Non-sterile products: 1.2.1.9 Pressurised preparations 1.2.2 Batch Certification
1.3	Biological medicinal products: Not applicable
1.4	Other products or manufacturing activity: Not applicable
1.5	Packaging: 1.5.1.9 Pressurised preparations 1.5.2 Secondary Packing
1.6	Quality Control testing: 1.6.3 Chemical/ Physical

2.	IMPORTATION OF MEDICINAL PRODUCTS
2.1	Quality control testing of imported medicinal products Not applicable
2.2	Batch certification of imported medicinal products Not applicable

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: P. A. Brown

Date: 14th October 2016

Name: Penny Brown

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