



CERTIFICATE OF GMP COMPLIANCE OF A CONTRACT TESTING SITE

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:

Company Name: **Animal & Plant Health Agency (APHA)**

Site address: Woodham Lane
New Haw
Addlestone
Surrey
KT15 3NB

Has been inspected in connection with Manufacturing / Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with Art. 80(1) of Directive 2001/82/EC transposed in the following national legislation:

The current Veterinary Medicines Regulations

From the knowledge gained during inspection of this contract testing site, the latest of which was conducted on **23rd – 24th January 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 contract testing 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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

Signature: Confidential

Date: 29 March 2019

Name: Confidential

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

1.1	Sterile Products: N/A
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: N/A
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.4 Biological

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

APHA conducts the following contract QC testing:

- Ph Eur 2.6.24 Avian Viral Vaccines: tests for extraneous agents in seed lots
- Ph Eur 2.6.25 Avian Live Virus Vaccines – tests for extraneous agents in finished product
- Other extraneous agent testing
- FMD Vaccines – finished product safety and potency testing

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

Signature: Confidential

Date: 29 March 2019

Name:

Confidential
Veterinary Medicines Directorate
tel: Confidential
email: Confidential