Ministry of Agriculture, Nature and Food Quality of the Netherlands

Certificate No: NL/V 19/0004

Medicines Evaluation Board - Veterinary Medicinal Products Unit

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC

The competent authority of the Netherlands confirms the following:

The manufacturer : Kernfarm B.V.

Site address : Corridor 14d (unit 4)
3621ZB Breukelen

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 2775-FGL in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation: Art. 2.19 of the Act Animals and art. 5.1 of the Decree on Veterinary Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on February 12, 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 en 2.
The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

MINISTRY OF AGRICULTURE, NATURE AND FOOD QUALITY
CHIEF VETERINARY OFFICER OF THE NETHERLANDS
THE HAGUE

Issue date: 06-06-2019	Name: drs. J.A. Jonis
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Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	**Sterile Products:**
	1.1.3. Batch certification
1.2	**Non-sterile products:**
	1.2.2. Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification (list of product types) 1.3.2.2 Immunological products
1.5	**Packaging**
	1.5.2 Secondary packing

Any restrictions or clarifying remarks related to the scope of this certificate :
Batch certification is only applicable on re-packed veterinary medicinal products with a marketing authorization for parallel-import.

Competent Authority of the Netherlands.

THE MINISTER OF STATE FOR ARICULTURE, NATURE and FOOD QUALITY,

per pro:

Utrecht, 06-06-2019

Dhr. drs. J.A. Jonis
Senior Regulatory Project Leader

MINISTRY OF AGRICULTURE, NATURE AND FOOD QUALITY
CHIEF VETERINARY OFFICER OF THE NETHERLANDS
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