



Certificate No: NL/V 17/0010

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 : Synergy Health Ede B.V.

Site address : Soevereinstraat 2
4879 NN Etten-Leur

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 1242-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 13 April 2017, 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.



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|------------------------|------------------------|
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Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

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|------------|--|
| 1.4 | Other products or manufacturing activity |
| | 1.4.2 <i>Sterilisation of active substances/excipients/finished product:</i> |
| | 1.4.2.5 Gamma irradiation |

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

The State secretary of Economic Affairs,

per pro:

Utrecht, 23-05-2017

Dhr. Ir. F. Verheijen

Head of the Veterinary Medicinal Products Unit



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