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Termőföldtől az asztalig

National Food Chain Safety Office
Directorate of Veterinary Medicinal Products



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Certificate No: CG-HU/02V/2016.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of **Hungary** confirms the following:

The manufacturer **European Pharma Hub Kft.**
Site address **2360 Gyál, 7000/9 hrsz., Hungary**

Has been inspected under the national inspection programme in connection with manufacturing authorisation No. **MA-HU/03V/2014./M1** in accordance with Art. 44 of Directive 2001/82/EC/ transposed in the following national legislation:

34. § (1) g) of Act XLVI of 2008 on the food chain and on its official control and 43. § (1), (2), (3) and 44. § (1), (2) of Decree 128/2009. (X. 6.) of the Minister of Agriculture and Rural Development on veterinary medicinal products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **05/11/2015**, it is considered that it complies with **the principles and guidelines of Good Manufacturing Practice laid down in 91/412/EEC¹**.

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.

¹These requirements fulfil the GMP recommendations of WHO.

Authorisation No.: MA-HU/03V/2014./M1


Signature: **Dr. Gábor Kulcsár**
Director
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Directorate of Veterinary Medicinal Products
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18/01/2016

Part 2

Veterinary Medicinal Products

I MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS

1.1	Sterile products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2 Batch certification</i>
1.5	Packaging
	<i>1.5.2 Secondary packing</i>

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

GMP certificate covers secondary packing plant in the building No. 15. and 16. of Akácliget Logisztikai Központ.

16/03/2016

Name and signature of the authorised person of the
Competent Authority of Hungary



Dr. Gábor Kulcsár
Director

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