

***National Food Chain Safety Office, Directorate of Veterinary Medicinal  
Products***

CERTIFICATE NUMBER: *CG-HU/02V/2020.*

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER** <sup>1, 2</sup>

**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: ***Magyar Tejgazdasági Kísérleti Intézet Korlátolt Felelősségű Társaság,  
Kutató-Élelmiszervizsgáló és Nyerstej Minősítő Laboratóriuma, Mikrobiológiai Laboratórium***  
Site address: ***Lucsony u. 24., Mosonmagyaróvár, H-9200, Hungary***

Has been inspected under the national inspection programme in connection with manufacturing  
authorisation no. ***MA-HU/02V/2009/MI.*** 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  
***2019-10-30*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC <sup>3</sup>

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 EudraGMDP. If it does not appear, please contact the issuing authority.

<sup>1</sup> The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports  
coming from third countries into a Member State.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

## Part 2

Veterinary Medicinal Products	
<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i>

2020-01-21

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



*Mr. Gábor Kulcsár*  
National Food Chain Safety Office, Directorate of  
Veterinary Medicinal Products  
Tel: +36 1 2629579  
Fax: +36 1 2622839