

MAGYAR TEJGAZDASÁGI  
KÍSÉRLETI INTÉZET KFT.  
ÉRK.: 2019. SZEPTEMBER 5.  
IKT.SZ.: 49003823

*National Institute of Pharmacy and Nutrition*

CERTIFICATE NUMBER: *OGYÉI/49341-4/2019*

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

**Part 1**

Issued following an inspection in accordance with :  
Art. 111(5) of Directive 2001/83/EC as amended  
Art. 15 of Directive 2001/20/EC

The competent authority of Hungary confirms the following:

The manufacturer: *Magyar Tejgazdasági Kísérleti Intézet Korlátolt Felelősségű Társaság  
Kutató-Élelmiszervizsgáló és Nyerstej Minősítő Laboratóriuma (MTKI Kft. Kutató-Élelmiszervizsgáló és  
Nyerstej Minősítő Laboratóriuma)/Hungarian Dairy Research Institute Ltd. Research – Food and Raw  
Milk Testing Laboratory (HDRI Ltd. Research – Food and Raw Milk Testing Laboratory)*  
Site address: *Lucsony u. 24, Mosonmagyaróvár, 9200, Hungary*

Has been inspected under the national inspection programme in connection with manufacturing  
authorisation no. *HU-M-MTKI* in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of  
Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on  
*2017-02-16* , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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**

Human Medicinal Products
Human Investigational Medicinal Products

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

<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.2 Microbiological: non-sterility</i>

2019-09-02

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



**Dr. Lukacs Ferenc**  
**National Institute of Pharmacy and Nutrition**

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