Nemzeti Élelmiszerlánc-biztonsági Hivatal
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Iktatószám: 02.2/1417-4/2018.

Certificate No: CG-HU/04V/2018.

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 **M-Teszt Mikrobiológiai Ellenőrző Kft.**
Site address **Fő út 200., Galgahévíz, H-2193, Hungary**

Has been inspected under the national inspection programme in connection with manufacturing authorisation No. **MA-HU/05V/2008/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 **18/02/2018**, it is considered that it complies with **The principles and guidelines of Good Manufacturing Practice laid down in 91/412/EEC**[1].

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.

[1] These requirements fulfil the GMP recommendations of WHO.

Nemzeti Élelmiszerlánc-biztonsági Hivatal

02/05/2018

Signature: **Dr. Gábor Kulcsár**
Director
National Food Chain Safety Office
Directorate of Veterinary Medicinal Products
H-1107 Budapest, Szállás u. 8.
+36-1-433-0330; Fax: +36-1-262-2839

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potential hazardous active ingredients this should be stated under relevant product type and dosage form.

1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility

Date: 02/05/2018

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

Nemzeti Élelmiszerlánc-biztonsági Hivatal 52

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Dr. Gábor Kulcsár
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