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National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: ***OGYÉI/9215-3/2017***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

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: ***Richter Gedeon Vegyészeti Gyár Nyilvánosan Működő Részvénytársaság (Richter Gedeon Vegyészeti Gyár Nyrt.)/Chemical Works of Gedeon Richter Plc.(Gedeon Richter Plc.)***
Site address: ***Gyömrői út 19-21., Budapest, 1103, Hungary***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***HU-M-RICH*** 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 ***2016-04-22*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

[1] *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.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.2 Lyophilisates Special Requirements 7 Other: including citostatics(en) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: Powders and granules(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: including antibiotics(en) 1.2.1.13 Tablets Special Requirements 7 Other: including products with hormonal activity(en) 1.2.1.17 Other: Vaginal rings with hormonal activity(en)
	1.2.2 Batch certification

1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: Biological active starting materials(en)
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: Powders and granules(en) 1.5.1.11 Semi-solids Special Requirements 7 Other: including antibiotics(en) 1.5.1.13 Tablets Special Requirements 7 Other: including products with hormonal activity(en) 1.5.1.17 Other non-sterile medicinal products: Vaginal rings with hormonal activity.(en)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*

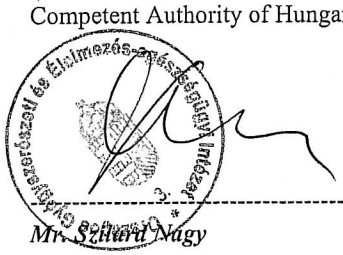
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

Authorized for manufacturing and packaging of vaginal rings with hormonal activity for Human Investigational products only. For 1.6 Quality control testing: including quality control testing of active substances and raw materials.

2017-02-23

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



Mr. Szilard Nagy
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Dr. Záborszky Eszter közjegyző
1106 Budapest, Örs vezér tere 25/A. III. emelet
Telefon: 431-0056, 431-0057 (hagyaték)
e-mail: iroda@zaborszkye.hu

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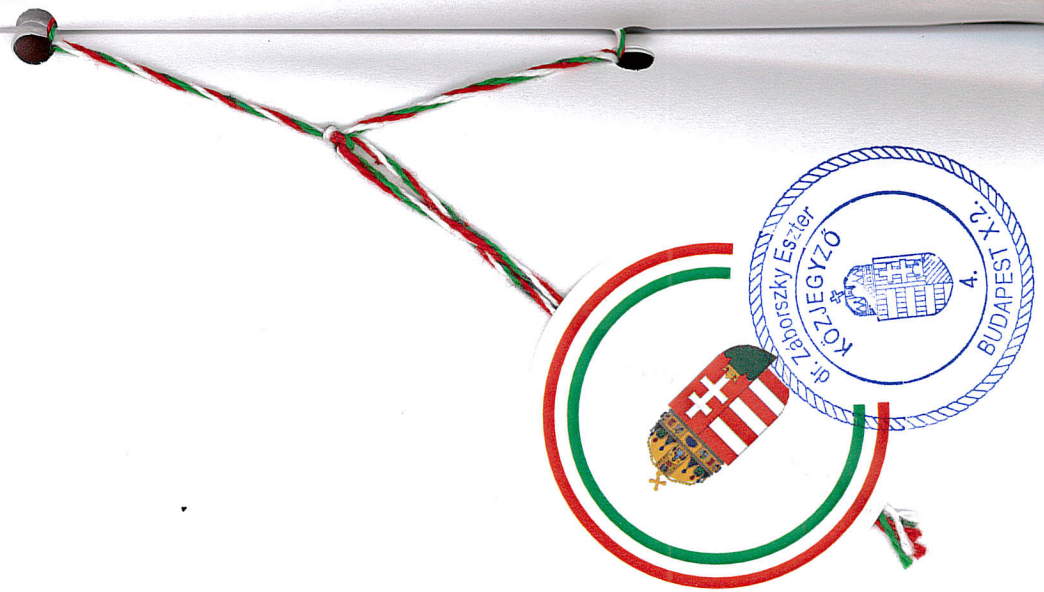
--- I hereby certify that this certified copy attached hereto is the true and correct copy of the original document „CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER" consisting of 4 (four) numbered pages with seal and signature on the last page, without stamp and duty stamp as presented before me.----------
Budapest, this 26th (twenty-sixth) day of April in the year of 2017 (two thousand and seventeen).----------

Dr. Záborszky Eszter KÖZJEGYZŐ 4. BUDAPEST X/2.

Dr. Ferenczy Réka
Notary Substitute


dr. Zaborszky Eszter
KÖZJEGYZŐ
4.
BUDAPEST X.ker.

APOSTILLE

(Convention de la Haye du 5 octobre 1961)

1. Ország:
   Country: **MAGYARORSZÁG**
   HUNGARY

Ezt a közokiratot
This public document

2. Írta alá:
   Has been signed by: Dr. Ferenczy Réka

3. Minőségében eljárva:
   Acting in the capacity of: közjegyző helyettes / Notary substitute

4. Az okirat pecsétjével (bélyegzőlenyomatával) van ellátva:
   Bears the seal / Stamp of: Dr. Záborszky Eszter közjegyző / Notary

Tanúsítja
Certified

5. Helység:
   At: Budapest

6. Időpont:
   Date: 2017. (év) (year) 05. (hónap) (month) 09. (nap) (day)

7. Kiállító:
   By: Magyar Országos Közjegyzői Kamara
   Hungarian Chamber of Civil Law Notaries

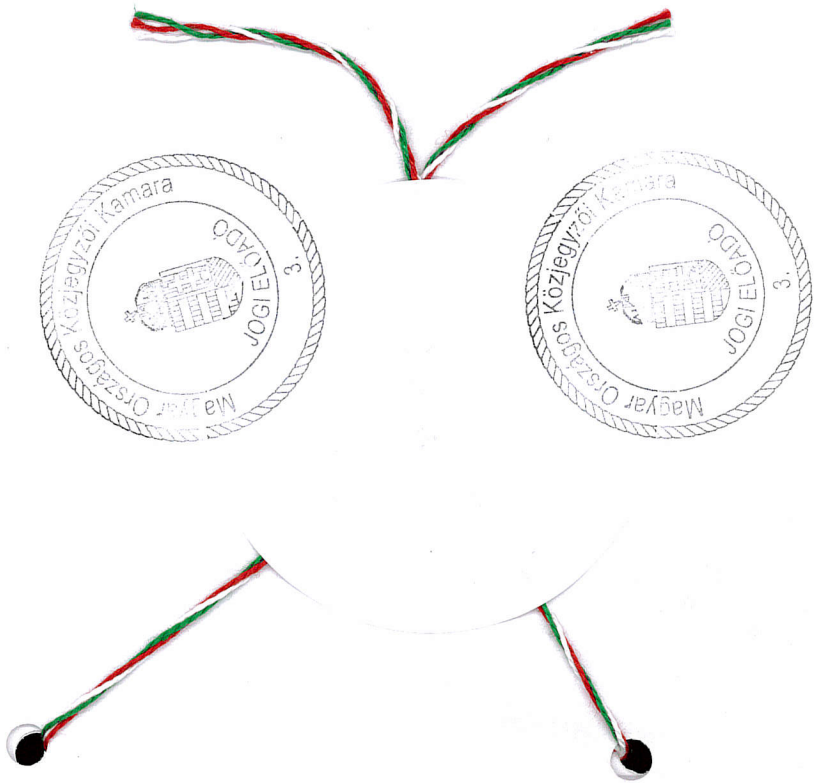
8. Ügyszám:
   No.: A01/2017/4279/2

9. Pecsét (bélyegzőlenyomat):
   Seal/Stamp:

Magyar Országos Közjegyzői Kamara
JOGI ELŐADÓ
3.

10. Aláírás:
    Signature:

Dr. Ágostonné dr. Kürthy Márta
apostille ügyintéző


Magyar Országos Közjegyzői Kamara
JOGI ELŐADÓ
3.