NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Directorate for Drug Inspection

National Center For Public Health And Pharmacy

CERTIFICATE NUMBER: *NNGYK/GYSZ/15826-7/2024*

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

Part 1

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

The competent authority of Hungary confirms the following:
The manufacturer: ***Teva Gyogyszergyar Zrt.***
Site address: ***Pallagi Ut 13, Debrecen, 4042, Hungary***
OMS Organisation Id. / OMS Location Id.: ***ORG-100000650 / LOC-100000645***

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-03-28***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 15 of Directive 2001/20/EC and Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
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 Special Requirements 7 Other: including products with hormonal activity(en) 1.2.1.2 Capsules, soft 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: microcapsules and powders(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: including products with hormonal activity(en) 1.2.1.12 Suppositories 1.2.1.13 Tablets Special Requirements 7 Other: including products with hormonal activity(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: including products with hormonal activity(en) 1.5.1.2 Capsules, soft 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: microcapsules and powders(en) 1.5.1.11 Semi-solids Special Requirements 7 Other: including products with hormonal activity(en) 1.5.1.12 Suppositories 1.5.1.13 Tablets Special Requirements 7 Other: including products with hormonal activity(en)
	1.5.2 Secondary packaging

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
	2.1.4 Biological
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Any restrictions related to the scope of this certificate:

Certificate includes activities concerning IMPs.

Clarifying remarks (for public users)

Certificate includes activities concerning IMPs.

2024-05-14

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

Andras Mittner
National Center For Public Health And Pharmacy
Tel:
Fax:

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Angol nyelvi jogosítvány száma: 8/2020
Olasz nyelvi jogosítvány száma: 9/2020

File no.: 32016/Z/559/2024
(licence to act in English No.: 8/2020)

---------- **Notarial certificate** ----------

--- I do hereby certify that this photocopy attached hereto is a true and faithful copy of the 3, i.e. three pages document with the name of "CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER" presented to me.----------

-- Having seen the presented document by simple inspection, it seems to be an original document. ----------

-- Having seen the presented document by simple inspection, it did not include any changes, damage or other disconcerting feature. ----------

-- Dated in Debrecen, this 11th (eleventh) day of June in the year of 2024 (two thousand and twenty-four).----------

Dr. Molnár, Tamás
Civil Law Notary

dr. Molnár Tamás KÖZJEGYZŐ 4. DEBRECEN 5.


dr. Molnár Tamás
KÖZJEGYZŐ
4.
DEBRECEN 5.

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. Molnár Tamás**

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

4. Az okirat pecsétjével (bélyegzőlenyomatával) van ellátva: / bears the seal/stamp of: **dr. Molnár Tamás közjegyző / Notary**

Tanúsítja
Certified

5. Helység: / At: **Budapest**

6. Időpont: / Date: **2024.** (év / year) **06.** (hónap / month) **24.** (nap / day)

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

8. Ügyszám: / No.: **A01/2024/7332/2**

9. Pecsét (bélyegzőlenyomat) / Seal/Stamp:

Magyar Országos Közjegyzői Kamara
JOGI ELŐADÓ
2.

10. Aláírás: / Signature:

dr. Bárdos Judit
jogi előadó


Magyar Országos Közjegyzői Kamara
JOGI ELŐADÓ
2.


Magyar Országos Közjegyzői Kamara
JOGI ELŐADÓ
2.