

National Center For Public Health And Pharmacy

CERTIFICATE NUMBER: **OGYÉI/18953-8/2021**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with

The competent authority of Hungary confirms the following:

The manufacturer: ***Teva Gyógyszergyár Zrt.***

Site address: ***Site1; Pallagi út 13., Debrecen, 4042, Hungary***

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 ***2021-04-01***, it is considered that it complies with:

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 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 Interpretation of the Union format for GMP certificate.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<p><i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i></p> <p>1.2.1.1 Capsules, hard shell Special Requirements 7 Other: including products with hormonal activity(en)</p> <p>1.2.1.2 Capsules, soft shell</p> <p>1.2.1.5 Liquids for external use</p> <p>1.2.1.6 Liquids for internal use</p> <p>1.2.1.8 Other solid dosage forms: microcapsules and powders(en)</p> <p>1.2.1.11 Semi-solids Special Requirements 7 Other: including products with hormonal activity(en)</p> <p>1.2.1.12 Suppositories</p> <p>1.2.1.13 Tablets Special Requirements 7 Other: including products with hormonal activity(en)</p>
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<p><i>1.5.1 Primary Packaging</i></p> <p>1.5.1.1 Capsules, hard shell Special Requirements 7 Other: including products with hormonal activity(en)</p> <p>1.5.1.2 Capsules, soft shell</p> <p>1.5.1.5 Liquids for external use</p> <p>1.5.1.6 Liquids for internal use</p> <p>1.5.1.8 Other solid dosage forms: microcapsules and powders(en)</p> <p>1.5.1.11 Semi-solids Special Requirements 7 Other: including products with hormonal activity(en)</p> <p>1.5.1.12 Suppositories</p> <p>1.5.1.13 Tablets Special Requirements 7 Other: including products with hormonal activity(en)</p>
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<p><i>1.6.2 Microbiological: non-sterility</i></p> <p><i>1.6.3 Chemical/Physical</i></p> <p><i>1.6.4 Biological</i></p>

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.2 <i>Microbiological: non-sterility</i>
	2.1.3 <i>Chemical/Physical</i>
	2.1.4 <i>Biological</i>
2.2	Batch certification of imported medicinal products
	2.2.2 <i>Non-sterile products</i>
2.3	Other importation activities
	2.3.1 <i>Site of physical importation</i>
	2.3.2 <i>Importation of intermediate which undergoes further processing</i>

Clarifying remarks (for public users)

Certificate includes activities concerning IMPs.

2021-07-14

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

Confidential
National Institute of Pharmacy and Nutrition
Tel:***Confidential***
Fax:***Confidential***