Zāļu valsts aģentūra

CERTIFICATE NUMBER: ***ZVA/LV/2019/002H***

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

The competent authority of Latvia confirms the following:
The manufacturer: ***FSUE "Moscow Endocrine Plant"***
Site address: ***25, Novokhokhlovskaya St., Moscow, 109052, Russian Federation***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:
Cabinet Regulation No. 304 (Adopted 18 April 2006) § 79 "Regulations Regarding the Procedures for the Manufacture and Control of Medicinal Products, Requirements for the Qualification and Professional Experience of a Qualified Person and the Procedures for the Issuance of the certificate of Good Manufacturing Practice to a Medicinal Products Manufacturing Undertaking"

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-12-08*** , 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.

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[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

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

The Certificate is restricted to Trametalin 50 mg/ml solution for injection 2 ml for product registration purposes only, till December 8, 2020. 1.6.4. Biological testing - bacterial endotoxins

2019-02-04

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

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Confidential
Latvian State Agency of Medicines
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