Zāļu valsts aģentūra

CERTIFICATE NUMBER: ***ZVA/LV/2019/020H***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Latvia confirms the following:
The manufacturer: ***Scientific industrial Centre "Borshchahivskiy Chemical Pharmaceutical Plant" Public Joint-Stock Company***
Site address: ***17, Myru Str, Kyiv, 03134, Ukraine***

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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-04-12***, 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. 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.*

Digitally signed by Chirtoacă Iurie
Date: 2023.01.31 15:06:04 EET
Reason: MoldSign Signature
Location: Moldova

Part 2

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.6 Other: powders for solution for injection/infusion(en) Special Requirements 1 B-lactam Antibiotics
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Workshop of sterile antibiotics No 2				***confidential***
Workshop No 1				***confidential***
Workshop No 3				***confidential***

Clarifying remarks (for public users)

Certificate has been re-issued in order to update the name and address of manufacturing site

2019-12-11

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

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Confidential
Latvian State Agency of Medicines
Tel:***Confidential***
Fax:***Confidential***