Agency For Medicinal Products And Medical Devices Of Croatia

CERTIFICATE NUMBER: ***530-10/22-05/07; 381-13-08/310-23-14***

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 Croatia confirms the following:
The manufacturer: ***Vem Ilac Sanayi Ve Ticaret A.S.***
Site address: ***Bahceagil Mahallesi, Caddesi Mah Fatih Bulvari No 38 Cerkezkoy Organize Sanayi Bolgesi Karaagac, Kapakli, 59510, Turkey***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034626*** / ***LOC-100054938***

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 ***2022-11-25***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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 Art. 111(5) of Directive 2001/83/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: 2023.08.15 08:37:57 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids 1.1.1.6 Other: Powder for solution for injection or infusion(en)
	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 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
		Ampoule-1 Line		***confidential***
		Sterile Powder Line		***confidential***

2023-07-10

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

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Confidential
Agency For Medicinal Products And Medical Devices Of Croatia
Tel:***Confidential***
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