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ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА

CERTIFICATE NUMBER:***BG/GMP/2022/198***

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 Bulgaria confirms the following:

The manufacturer: ***Onko Ilac San. Ve TiC. A.S.***

Site address: ***Organize Sanayi Bolgesi, 1700 Sokak No 1703, Gebze, 41480, Turkey***

OMS Location: ***LOC-100030006***

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 ***2021-12-21***, 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.

(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.

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)
1.1.1.1 Large volume liquids
1.1.1.2 Lyophilisates
1.1.1.4 Small volume liquids
1.1.2 Terminally Sterilised (processing operations for the following dosage forms)
1.1.2.1 Large volume liquids
1.1.2.3 Small volume liquids

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

4. Other Activities - Active Substances:
This inspection covers Facility A and Facility B of the manufacturing site: - Sterile products: Aseptically prepared, large and small volume liquids and Terminally sterilised, large and small volume liquids (Facility A and Facility B); - Sterile products: Aseptically prepared, Lyophilisates (Facility B); - Non-sterile products: tablets and film-coated tablets (Facility B).

Clarifying remarks (for public users):
It has been a distant inspection.

Digitally signed by Chirtoaca Iurie
Date: 2022.07.21 18:16:38 EEST
Reason: MoldSign Signature
Location: Moldova

2022-02-01

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

Confidential

Bulgarian Drug Agency

Tel:***Confidential***

Fax:***Confidential***