

GMP Compliance Menu

Search

[GMP Certificates](#)[Non-Compliance Report](#)

Print Preview

Print Preview (Short version)

Back To Search

ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВОВАТА

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.

2022-02-01

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

Confidential**Bulgarian Drug Agency**Tel: **Confidential**

The EudraGMDP database is maintained and operated by the EMA. Access to the general public is granted in order to enhance availability of information related to the EMA mandate. The content of the database is provided by the National Competent Authorities (NCA) of the EEA. For this reason, the EMA accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this database. Any questions about the content should be addressed to the relevant NCA. Please [click here](#) to get list of NCA's.

Due to the restrictions caused by COVID-19, the period of validity of MIA's, VDA's, GMP and GDP certificates is automatically extended until the end of 2022, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are conducted where and when possible. Competent authorities reserve the right to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP/GDP certificates, as appropriate

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMDP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on [EMA's website](#)