EudraGMDP

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State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania

CERTIFICATE NUMBER: ***LT/07H/2019***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER *(1), (2)*

Part 1

Issued following an inspection in accordance with :

The competent authority of Lithuania confirms the following:

The manufacturer: **Private Joint Stock Company "Pharmaceutical firm "Darnitsa"**

Site address: **13 Boryspilska street, Kyiv, 02093, Ukraine**

Other

(Human) Has been inspected in connection with contract manufacturer located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation: Law on Pharmacy 22 June 2006 No X-709.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-07-05***, 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.

Digitally signed by Harea Ștefan
Date: 2023.03.03 09:37:59 EET
Reason: MoldSign Signature
Location: Moldova

(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

1 MANUFACTURING OPERATIONS
1.1 Sterile products
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
1.5 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* *1.6.4 Biological*

4. Other Activities - Active Substances:
Fluconazole IBE 2 mg/ml solution for infusion 100 ml bottle LT/1/17/4063/001 Furosemide IBE 10 mg/ml 2 ml amp. N10 solution for injections or infusions LT/1/17/4155/001 Glucose IBE 50 mg/ml solution for infusion 250 ml, 500 ml bottle LT/1/17/4060/001-002 Magnesium sulfate heptahydrate IBE 250 mg/ml solution for injections/infusions 5 ml amp. N10, 10 ml amp. N10 LT/1/17/4110/001-003 Sodium chloride IBE 9 mg/ml 5 ml amp. N10 solution for injections LT/1/17/4062/001-002 Sodium chloride IBE solution for infusion 250 ml, 500 ml bottle LT/1/17/4062/003

2019-09-05

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

Confidential

State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania

Tel:***Confidential***

Fax:***Confidential***

Due to the restrictions caused by COVID-19, the period of validity GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2023, except where clarifying remarks in the document state otherwise. Manufacturers, and 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 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