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GMP Compliance Menu

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Agencia Națională a Medicamentului și a Dispozitivelor Medicale din România

CERTIFICATE NUMBER:006/2017/RO

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{(1), (2)}

Part 1

Issued following an inspection in accordance with :

The competent authority of Romania confirms the following:

The manufacturer: **YURIA PHARM LTD**

Site address: **108 Verbovetskogo St., Cherkassy, 18030, 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 **2016-08-25**, 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.

⁽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
1.2 Non-sterile products
1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
1.5 Packaging
1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 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

Clarifying remarks (for public users):

First Floor - total manufacturing operations are carried out for sterile products – terminally sterilized – large volume parnterals packaged in glass vials; Second Floor - total manufacturing operations are carried out for sterile products – terminally sterilized – small volume liquids packaged in glass vials and for non-sterile products - liquids for internal use (solutions, syrups) packaged in plastic bottles; finished product warehouse no.2 at the address 21 Chygyrynska St, Cherkasy, 18030, Ukraine; for Rifonat 30mg/ml concentrate for solution for infusion, and Paskonat 30mg/ml solution for infusion the compliance status does not apply until a new manufacturing process is developed and validated. This Certificate is valid until February 2018

2017-02-14

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

Confidential

National Agency for Medicines and Medical Devices

Tel: **Confidential**

Fax: **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 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](#)

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