National Agency for Medicines and Medical Devices of Romania

CERTIFICATE NUMBER :***006/2017/RO***

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 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 :

- 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 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

Human Medicinal Products

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***

Digitally signed by Chirtoacă Iurie
Date: 2021.09.28 12:10:08 MSK
Reason: MoldSign Signature
Location: Moldova

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, WDA's, GMP and GDP certificates is automatically extended until the end of 2021. On-site inspections will resume as soon as there is a consensus that the period of the public health crisis has passed. The clarifying remark section of individual MIA's, WDA's, GMP and GDP certificates will indicate any exceptions. Competent authorities reserve the right to inspect a manufacturing site should the need arise.

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