ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ
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January 10, 2018

JSC "AVVA RUS", Kirov branch

Inspection of the medicinal products´ manufacturing facility: JSC "AVVA RUS", Kirov branch, Building 18
Inspection no.: 29/2017, date inspection ended: 19 July 2017
Good Manufacturing Practice (GMP) Certificate no.: AVVA RUS18 2018/01

Please find, herewith attached, the GMP Certificate for the above mentioned manufacturing facility.

The Certificate is issued in accordance to the provisions of article 48 (14) of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No. 70(I) of 2001 *[Article 111(5) of the Directive 2001/83/EC]*.

This Certificate is also published in the EudraGMP European Database (http://eudragmp.eudra.org/).

Anna Paphitou
Head GMP Inspector
Pharmaceutical Services
Ministry of Health

Pharmaceutical Services Ministry Of Health

CERTIFICATE NUMBER: ***AVVA RUS18 2018/01***

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 Cyprus confirms the following:
The manufacturer: ***JSC AVVA RUS Kirov Branch bulding 18***
Site address: ***53a Luganskaya Street, Kirov, 610044, Russian Federation***

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 transposed in the following national legislation:
PART IV, Chapters A and B of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law No 70(I) of 2001, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-07-19*** , 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.

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[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	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: powders for oral suspension(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: powder for oral suspension(en) 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

JSC AVVA RUS Building 18, manufactures only oral penicillin antibiotics (Tablets, capsules and powder for oral suspension)

2018-01-09

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

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