Regierungspraesidium Tuebingen, Leitstelle Arzneimittelueberwachung Baden-Wuerttemberg

CERTIFICATE NUMBER : ***DE_BW_01_GMP_2013_0131***

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 Germany confirms the following:
The manufacturer :***DEVA***
Site address :***Ulus Mah. Ankara Cad. No. 2, Kartepe - Kocaeli, TR-41135, Turkey***

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 ***2013-10-11*** , 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.*

Digitally signed by Chirtoacă Iurie
Date: 2022.01.05 11:33:05 EET
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

Manufacturing with Blow-Fill-Seal-Technology only. Inspection and issuance of this GMP certificate were done as competent authority for the importer Regiomedica GmbH, Teichstr. 66 in D-79539 Loerrach (Germany) regarding the following medicinal products/active pharmaceutical ingredients: - Azelastin eye drops - Diclofenac eye drops - Ofloxacin eye drops - Glucose solution for infusion - Sodium chloride solution for infusion The GMP certificate is valid for the medicinal products with the production steps mentioned above and for the corresponding premises according to the lay-outs dated May 03, 2013. The current validity of this certificate should be verified with EudraGMP.

2013-11-21

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

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Confidential
Regierungspraesidium Tuebingen, Leitstelle Arzneimittelueberwachung Baden-Wuerttemberg
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