Regierungspräsidium Darmstadt

CERTIFICATE NUMBER: ***DE_HE_01_GMP_2016_0069***

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: ***Sanofi-Aventis Vostok***
Site address: ***Livenskaya str. 1, Bolshekulikovskoye, Orlovskiy rayon, Orlovskaya obl., 302516, s/p, Russian Federation***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2014-10-10*** , 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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The time limit 09.10.2016 was cancelled effective from 01.09.2016. The certificate now is valid until 09.10.2017. Scope of inspection: Insuman Rapid (100IU/ml) 3 ml cartridges Lantus (100IU/ml) 3 ml cartridges Apidra (100IU/ml) 3 ml cartridges European Union only valid in connection with the current confirmation according to para 72a section 1 sentence 1 number 2 Medicinal Products Act, the German Drug Law (Arzneimittelgesetz AMG), issued to the importing company Sanofi Aventis Deutschland GmbH, Brueningstrasse 50, 65926 Frankfurt a.M. after the inspection according to para 72a section 1 sentence 2 number 1 Medicinal Products Act, and after confirming the validity of the inputs using the database according to para 67a Medicinal Products Act.

2016-09-01

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

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