11 JUNI 2014

EUROSTATION II
Victor Hortaplein 40 bus 40
1060 BRUSSELS (BELGIUM)
http://www.fagg-afmps.be

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2014/008***

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 Belgium confirms the following:
The manufacturer: ***Ajinomoto OmniChem NV***
Site address: ***Cooppallaan 91, Wetteren, B-9230, Belgium***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
Article 12 bis, § 1 of the Law of 25th March 1964 related to the Medicinal Products and Article 80 of the royal decree of 14 December 2006 related to medicinal products for human and veterinary use

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2014-03-19*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

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 authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

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Part 2

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: active ingredients(en)

[redacted]

[redacted] ***ROSUVASTATIN,*** [redacted]
FULVESTRANT, GEFITINIB, [redacted] ***QUETIAPINE FUMARATE***

[redacted]

2014-06-02

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

Philippe DE BUCK

DG Inspection
Head of Division Authorisations

Mr Xavier De Cuyper
Federal Agency for Medicines and Health Products
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Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten

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