Agenzia Italiana del Farmaco

AIFA

Certificate No: **IT/GMP/E/6-2014**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer
Eurofins Lancaster Laboratories, Inc.
Site address:
2425 New Holland Pike,
Lancaster, PA, 17601- USA

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: D.lgs 219/06 Art. 53.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2014-01-31**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

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Part 2

Name and address of the site: **Eurofins Lancaster Laboratories, Inc.**
2425 New Holland Pike,
Lancaster, PA, 17601- USA

Human Medicinal Products

Authorised Operations Manufacturing Operations	
1 - MANUFACTURING OPERATIONS	
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**

2014-04-17

Name and signature of the authorised person of the Competent Authority of Republic of Italy

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Dott. Renato Massimi
AIFA – Manufacturing Authorization Unit
Tel: +39 06 59784477
Fax: +39 06 59784312