Agency for Medicinal Products
and Medical Devices
of the Republic of Slovenia

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Javna agencija Republike Slovenije za zdravila in medicinske pripomočke

CERTIFICATE NUMBER: ***450-12/2012-2***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Slovenia confirms the following:

The manufacturer: **KEMIJSKI INŠTITUT**

Site address: ***Hajdrihova 19, 1001 Ljubljana, Slovenia***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***506-0002/010-8*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 44 of Directive 2001/82/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2011-10-07*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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. This certificate is valid only when presented with all pages and both Parts 1 and 2.
The authenticity of this certificate may be verified with the issuing authority.

Part 2

Human Medicinal Products
Veterinary Medicinal Products
1 Manufacturing Operations
1.6 Quality control testing
1.6.3 Chemical/Physical

2012-05-16

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

Mr Andrej Golmajer Golmajer, 16.05.2012

Javna agencija Republike Slovenije za zdravila in medicinske pripomočke

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REPUBLIKA SLOVENIJA