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Agency for medicinal products and medical devices of the Republic of Slovenia

CERTIFICATE NUMBER:

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
Art. 80(5) of Directive 2001/82/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Slovenia confirms the following:
The manufacturer:

Site address:

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***800-6/2014-7*** in accordance with Art. 40 of Directive 2001/83/EC , Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2013-10-30*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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 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).*

Number:
Date: 10 -11- 2014

Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke
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of the Republic of Slovenia

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Issued on the request of the

Slovenia

STATEMENT

The Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia, I , Slovenia

certifies herewith that

Slovenia

at the manufacturing plant

Slovenia

Is manufacturer of active substances/blends

This is also to certify that the manufacturing plant in which the product is produced is subject to inspections at suitable intervals and the manufacturer meets the requirements for good practice in the manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed in the country of origin or to be exported.

Name of authorized person:

MSc. (Pharm.)
Director

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE
15 11
REPUBLIKA SLOVENIJA

Obr. 364-02