

Certificate No: 450-8/2011-2

Date: March 7, 2011

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 **Slovenia**:

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

confirms the following:

The manufacturer: **LEX d.o.o.**

Site address: **Vanganelška cesta 26, 6000 Koper, Slovenia**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **401-2078/08-2** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Medicinal Products Act (OJ RS, No. 31/2006, 45/08)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on: **13th December, 2010**

it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC and Directive 91/412/EEC.

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.

Janez Obreza, B.Sc. (Pharm.)

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Pharmaceutical GMP/GDP Inspector



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Part 2

Clarifying remarks related to the scope of this certificate:

LEX d.o.o. is authorised for Repackaging, Quality control testing (Chemical/Physical) and Batch certification of Active Pharmaceutical Ingredients.

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

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*Janez Obreza, B.Sc. (Pharm.)
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