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

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

CERTIFICATE NUMBER: ***401-9/2015-5***

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: ***Lek farmacevtska družba d.d. (Lek Pharmaceuticals d.d.), Verovškova 57, Ljubljana, Slovenia***
Site address: ***Verovškova ulica 57, Ljubljana, 1526, Slovenia***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***800-30/2014-12*** 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 ***2015-05-18*** , 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 EudraGMP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, 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] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products
Veterinary Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Immunosuppressives(en) 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets Special Requirements 7 Other: Hormons or Substance with Hormonal Activity,Prostaglandins/Cytokines,Cytotoxics/Cytostatics(en) 1.2.1.17 Other: granules, granulate, pellets, micropellets, powders(en)
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.2 Secondary packing
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Immunosuppressives(en) 1.5.1.2 Capsules, soft shell 1.5.1.3 Chewing gums 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets Special Requirements 7 Other: Hormons or Substance with Hormonal Activity,Prostaglandins/Cytokines,Cytotoxics/Cytostatics(en) 1.5.1.17 Other non-sterile medicinal products
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.4 Other: Herbal products(en)

Any restrictions related to the scope of this certificate :

Importation of intermediate which undergoes further processing includes Capsules, hard and soft shell, Tablets and Granulate.

Clarifying remarks (for public users)

Importation of intermediate which undergoes further processing includes Capsules, hard and soft shell, Tablets and Granulate.

2015-08-19

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

Mr. Janez Obreza
Agency for medicinal products and medical devices of the Republic of Slovenia
Tel: ***+386 8 2000606***
Fax: ***+386 8 2000630***

...ar mag. BLAŽ HROVATIN, potrjuje,

... je to prepis originala listine – ~~overjenega prepisa~~ – ~~navadnega prepisa~~ listine dokument v tujem jeziku s številko 401-9/2015-5 z dne 19.08.2015

(označba listine)

Listina je pisana ~~ročno~~ – na ~~pisalni stroj~~ – z računalnikom. Listina ima 3 strani. Listina je opremljena s ~~pečatom~~ – z žigom – ~~s koleki~~

~~Izvirnik listine se po strankinem zahtevanju nahaja v~~

... je stranka predložila

... 24.08.2015

Notar

mag. BLAŽ HROVATIN
NOTAR
LJUBLJANA

Ministrstvo za pravosodje Republike Slovenije potrjuje pristnost podpisa mag. Blaž Hrovatin - notar - Ljubljana

in uradnega pečata notarja mag. Blaž Hrovatin

Taksa v znesku 1,35€ po tar. št. 9. Zakona o upravnih taksah je nalepljena in uničena na zaprosilu za overitev

Št.: 020-37/2015

Ljubljana, 25. 9. 2015

KATARINA KERŠMANC
višja svetovalka I

REPUBLIKA SLOVENIJA
MINISTRSTVO ZA PRAVOSODJE
08
Ljubljana

Seen and certified in the
Ministry of Foreign Affairs
of the Republic of Slovenia

Leg. No. 020-1166/15

Ljubljana, 25.9.2015

KATARINA PLAVŠIČ BARAGA

REPUBLIKA SLOVENIJA
MINISTRSTVO ZA ZUNANJE ZADEVE
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LJUBLJANA

CONSULADO DE CHILE EN VIENA, AUSTRIA

El Cónsul de Chile que suscribe certifica la autenticidad de la firma de don:

KATARINA PLAVSIC BARAGA

Oficial de Legalizaciones del Ministerio de Relaciones Exteriores de la República de Eslovenia.
Viena, 02 de Octubre de 2015.

CONSULADO DE CHILE EN VIENA · AUSTRIA ·

Ximena Verdugo Fuentes
Cónsul de Chile

Actuación N° 830 Arancel Art. N° 4/10
Derechos USD 12.- Diferencia 10% 1.20.-
Total percibido en USD 13.20.-
Pagado en moneda del país EUR 12.-
Viena, 02 de Octubre de 2015

LEGALIZADA EN EL MINISTERIO DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr. (a)
21 OCT 2015
Miguel REYES VARGAS
Oficial de Legalizaciones


CONSULADO DE CHILE EN VIENA
AUSTRIA