This translation consists of:	22 sheets / 22 pages
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Date:	21 January 2014

CERTIFIED TRANSLATION FROM CROATIAN LANGUAGE

STALNI SUDSKI TUMAČ ZA ENGLESKI JEZIK
COURT INTERPRETER FOR ENGLISH LANGUAGE - PERMANENT
Iva
Sunko, dipl.iur.
RIJEKA

(Croatian coat of arms)
REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

REPUBLIC OF CROATIA
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
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Class: UP/I-530-01/13-03/09
Docket No.: 381-13-04/151-13-05

In Zagreb, 19 December 2013

Agency for medicinal products and medical devices, upon request from , for issuing a manufacturing authorisation, based on Article 72, 77 and 212of the Medicinal Products Act (Official Gazette, number 76/13) and Article 96 of the General Administrative Procedure Act (Official Gazette, number 47/09) brings the following

DECISION

1. , is issued a manufacturing authorisation for complete manufacturing process and for partial manufacturing processes for manufacturing lines on location , for activities of medicinal products manufacture, packaging, physical-chemical quality control, import and storage of raw materials; on location , for activities of microbiological quality control – microbiological purity and sterility, storage of raw materials and batch release and for location for activities of storage and distribution of finished medicinal products; in accordance with enlisted in Addendum IA, Addendum IB and Addendum IC – Areas of performing the activities and pharmaceutical forms, which make integral part of this decision.

2. By bringing of this decision, decision from Agency for medicinal products and medical devices Class: UP/I-530-01/13-03/02, Docket No: 381-13-04/151-13-09 from 25 March 2013 ceases to be valid.

Statement of grounds

has submitted to the Agency for medicinal products and medical devices on 7 August 2013 the request for granting a new manufacturing authorization for complete manufacturing process and partial manufacturing processes for manufacturing lines on manufacturing locations:

- - for activities of medicinal products manufacture, packaging, physical-chemical quality control, import and storage of raw materials;
- - for activities of microbiological quality control – microbiological purity and sterility, storage of raw materials and batch release;
- - for activities of storage and distribution of finished medicinal products;

which was supplemented on 15 November 2013 and 2 December 2013.

Request for issuing a new manufacturing authorisation has been submitted due to alignment with provisions of Medicinal Products Act (Official Gazette, number 76/13) and Ordinance on Conditions for Issuing a Manufacturing Authorisations, on the Requirements of Good Manufacturing Practice and on the Certificate of Good Manufacturing Practice for Medicinal Products (Official Gazette, number 83/13) and i: 1 :tion of administrative changes:

- change of street number for location
- change of street number for location
- change company headquarters from
- change of approved qualified person for batch release Maša Pupovac, M.Pharm to surname Zec because of marriage.

Request if founded.

Acting upon the submitted request it was determined that the applicant delivered the requested documentation that contains information and documents prescribed by Article 75 of the Medicinal Products Act (Official Gazette, number 76/13).

According to Article 76 of the Medicinal Products Act (Official Gazette, number 76/13) and Article 26 of the Ordinance on Conditions for Issuing a Manufacturing Authorisations, on the Requirements of Good Manufacturing Practice and on the Certificate of Good Manufacturing Practice for Medicinal Products (Official Gazette, number 83/13), inspector of the Agency has given its opinion on the 16 December 2013 Class: 530-01/13-03/09, Docket No.: 381-13-04/151-13-04 on fulfillment of the conditions of good manufacturing practice for complete process and partial manufacturing processes and importation of medicinal products on manufacturing location

The opinion is given based on the documentation enclosed with the request for issuing a manufacturing authorisation and on the last conducted audit report. Audit for determining fulfilling the conditions of good manufacturing practice for in the process of issuing a manufacturing authorisation for manufacturer had been conducted by expert committee composed of pharmaceutical inspector of Ministry of Health and a member of Agency for medicinal products and medical devices in the period from 6 till 8 March 2013. Audit has been conducted according to then valid Medicinal Products Act (Official Gazette, number 71/07, 45/09 and 124/11) and the Ordinance on Conditions and Procedures of Establishing Requirements of Good Manufacturing Practice and the Procedure of Issuing Manufacturing Authorisation and Certificates of Good Manufacturing Practice (Official Gazette, number 74/09) and valid requirements of good manufacturing practice. Based on the conducted audit and the report on conducted audit (class: UP/I-530-01/13-03/02, docket no.: 381-13-04/151-13-07 from 18 March 2013) and the opinion of pharmaceutical inspector on fulfillment of the conditions of good manufacturing practice (class: 530-01/13-03/09, docket no.: 534-07-2-2/1-13-08 from 21 March 2013), Agency for medicinal products and medical devices has on 25 March 2013 issued a manufacturing authorisation for complete process and individual manufacturing processes for medicinal products (class: UP/I-530-01/13-03/02, docket no.: 381-13-04/151-13-09) for a period of 5 years. Article 238 of Medicinal Products Act (Official Gazette, number 76/13) has prescribed deadline of 12 months for adjustment with provisions of new Law for all medicinal products manufacturers to which manufacturing authorisation has been issued based on the Medicinal Products Act (Official Gazette, number 71/07, 45/09 and 124/11) and the Ordinance on Conditions and Procedures of Establishing Requirements of Good Manufacturing Practice and the Procedure of Issuing Manufacturing Authorisation and Certificates of Good Manufacturing Practice (Official Gazette, number 74/09). Enlisted Ordinance has ceased to be valid with coming into force of the Ordinance on Conditions for Issuing a Manufacturing Authorisations, on the Requirements of Good Manufacturing Practice and on the Certificate of Good Manufacturing Practice for Medicinal

Products (Official Gazette, number 83/13). Both Ordinances prescribe as a standard for good manufacturing practice Conditions and guidelines of good manufacturing practice for medicinal products and additional specifics for specific processes and pharmaceutical forms »The Rules Governing Medicinal Products in the European Union«, Volume 4 – Good Manufacturing Practices, Medicinal Products for Human and Veterinary use, and so the last audit on the manufacturer has been conducted according to valid standard.

In the opinion of inspector of the Agency (class: 530-01/13-03/09, docket no.: 381-13-04/151-13-04 from 16 December 2013) it has been listed that the applicant fulfills conditions of good manufacturing practice prescribed by the Law and the Ordinance.

Subsequently, in the conducted procedure it was determined that applicant fulfills all conditions of good manufacturing practice and that conditions for issuing a manufacturing authorisation for complete manufacturing process and partial manufacturing processes for medicinal products have been fulfilled for locations of and that based on Article 73 Paragraph 1, Article 76, 77 and 212 of Medicinal Products Act (Official Gazette, number 83/13) it was needed to be decided as stated in the disposition of this decision.

INSTRUCTION ON THE LEGAL REMEDY:

This decision if final in the administrative procedure and it is not possible to file an appeal against this decision, but within 30 days from delivery of this decision it is possible to initiate administrative dispute before Administrative Court according to place of jurisdiction.

The administrative fee in the amount of 300,00 kunas according to the Tariff no. 2 and Tariff no. 60 of the Administrative Tariff of the Tax Administrating Act (Official Gazette, no. 8/96, 77/96, 95/97, 131/97, 68/98, 66/99, 145/99, 116/00, 163/03, 17/04, 110/04, 141/04, 150/05, 153/05, 129/06, 117/07, 25/08, 60/08, 20/10, 69/10, 126/11, 112/12, 19/13 and 80/13) has been paid.

Director
(signature: unreadable)
Ph.D , MD
spec. of clinical pharmacology and toxicology

(Seal: round shape - Republic of Croatia 2 Zagreb Agency for Medicinal Products and Medical Devices)

Deliver to:

1. .
2. Archives-here

MANUFACTURING AUTHORISATION class: UP/I-530-01/13-03/09, docket no.: 381-13-04/151-13-05 from 19 December 2013

Addendum 1A - AREAS OF PERFORMING THE ACTIVITIES AND PHARMACEUTICAL FORMS OF MEDICINAL PRODUCTS (delete parts that are not applicable)
Annex 1A – SCOPE OF AUTHORISATION *(delete the section that do not apply)*

Name and address of manufacturing location:

Name and address of site:

☒ Medicinal products *Human Medicinal Product*

Authorised operations *Authorised operations* ☒ Manufacturing (PART I) *Manufacturing Operations (according to part 1)* ☒ Importation (PART 2) *Importation of Medicinal Products (according to part 2)*

PART 1. MANUFACTURING ***Part 1 – MANUFACTURING OPERATIONS***	
1.1	**Sterile medicinal products** ***Sterile products***
	1.1.1 Aseptically prepared medicinal products *Aseptically prepared* 1.1.1.4 Small volume liquids *Small volume liquids*
1.2	**Non-sterile medicinal products** ***Non-sterile products***
	1.2.1 Non-sterile medicinal products (manufacture in strict sense) *Non-sterile products (processing operations for the following dosage forms* 1.2.1.1 Hard capsules *Capsules, hard shell* 1.2.1.5 Liquids for external use *Liquids for external use* 1.2.1.6 Liquids for internal use *Liquids for internal use* 1.2.1.11 Semi-solid forms *Semi-solids* 1.2.1.13 Tablets *Tablets* 1.2.1.17 Other *Other:* Herbal tea *Herbal tea*
1.4	**Other medicinal products or manufacturing activities** ***Other products or manufacturing activities***
	1.4.1 Manufacturing: *Manufacture of:* 1.4.1.1 Herbal medicinal products *Herbal products*
1.5	**Packing** ***Packing***
	1.5.1 Primary packing *Primary packing* 1.5.1.1 Hard Capsules *Capsules, hard shell* 1.5.1.5 Liquids for external use *Liquids for external use* 1.5.1.6 Liquids for internal use *Liquids for internal use*

	1.5.1.11 Semi-solid forms *Semi-solids* 1.2.1.13 Tablets *Tablets* 1.5.1.17 Other *Other* Granules *Granules*
	1.5.2 Secondary packing *Secondary packing*
1.6	**Quality control *Quality control testing***
	1.6.3 Chemical/Physical testing *Chemical/Physical*

Limitation or explanations related to enlisted for manufacture:
Any restriction or clarification remarks related to scope of these Manufacturing operations:

Aseptically prepared medicinal products manufactured in are eye drops, nasal drops and nasal spray.
Aseptically prepared sterile products that are manufactured by . are eye drops, nasal drops and nasal spray.

PART 2. IMPORTATION OF MEDICINAL PRODUCTS *Part 2 – IMPORTATION OF MEDICINAL PRODUCTS*	
2.1	**Quality control of imported medicinal products** ***Quality control testing of imported medicinal products***
	2.1.3 Chemical/Physical testing *Chemical/Physical*
2.3	**Other importation activities** ***Other importation activities***
	2.3.1 Location of physical importation of medicinal product *Site of physical importation*
	2.3.2 Importation of intermediates for further manufacture *Importation of intermediate which undergoes further processing*

Limitation or explanations related to enlisted for importation: /
Any restriction or clarification remarks related to scope of these Importation operations: /

MANUFACTURING AUTHORISATION class: UP/I-530-01/13-03/09, docket no.: 381-13-04/151-13-05 from 19 December 2013

Addendum 1B - AREAS OF PERFORMING THE ACTIVITIES AND PHARMACEUTICAL FORMS OF MEDICINAL PRODUCTS (delete parts that are not applicable)
Annex 1B – SCOPE OF AUTHORISATION *(delete the section that do not apply)*

Name and address of manufacturing location:
JADRAN-GALENSKI LABORATORIJ d.d. (abbreviated company name: JGL d.d.)
Pulac 4A, 51000 Rijeka, Republic of Croatia

Name and address of site:
JADRAN-GALENSKI LABORATORIJ d.d. (abbreviated company name: JGL d.d.)
Pulac 4A, 51000 Rijeka, Republic of Croatia

☒ Medicinal products *Human Medicinal Product*

Authorised operations *Authorised operations* ☒ Manufacturing (PART I) *Manufacturing Operations (according to part 1)* ☒ Importation (PART 2) *Importation of Medicinal Products (according to part 2)*

PART 1. MANUFACTURING ***Part 1 – MANUFACTURING OPERATIONS***	
1.1	**Sterile medicinal products** ***Sterile products***
	1.1.3 Batch release from qualified person for batch release *Batch certification*
1.2	**Non-sterile medicinal products** ***Non-sterile products***
	1.2.2 Batch release from qualified person for batch release *Batch certification*
1.6	**Quality control** ***Quality control testing***
	1.6.1 Microbiological testing: sterility *Microbiological: sterility*
	1.6.2 Microbiological testing: microbiological purity *Microbiological: non-sterility*

Limitation or explanations related to enlisted for manufacture: /
Any restriction or clarification remarks related to scope of these Manufacturing operations: /

PART 2. IMPORTATION OF MEDICINAL PRODUCTS ***Part 2 – IMPORTATION OF MEDICINAL PRODUCTS***	
2.1	**Quality control of imported medicinal products** ***Quality control testing of imported medicinal products***
	2.1.1 Microbiological testing: sterility *Microbiological: sterility*
	2.1.2 Microbiological testing: microbiological purity *Microbiological: non-sterility*
2.2	**Batch release of imported medicinal products from qualified person for batch release** ***Batch certification of imported medicinal products***
	2.2.1 Sterile medicinal products *Sterile products* 2.2.1.1 Aseptically prepared medicinal products *Aseptically prepared* 2.2.1.1 Terminally sterilised medicinal products *Terminally sterilised*
	2.2.2 Non-sterile medicinal products *Non-sterile products*

Limitation or explanations related to enlisted for importation: /
Any restriction or clarification remarks related to scope of these Importation operations: /

MANUFACTURING AUTHORISATION class: UP/I-530-01/13-03/09, docket no.: 381-13-04/151-13-05 from 19 December 2013

Addendum 1C - AREAS OF PERFORMING THE ACTIVITIES AND PHARMACEUTICAL FORMS OF MEDICINAL PRODUCTS (delete parts that are not applicable)
Annex 1C – SCOPE OF AUTHORISATION *(delete the section that do not apply)*

Name and address of manufacturing location:
JADRAN-GALENSKI LABORATORIJ d.d. (abbreviated company name: JGL d.d.)
Osječka 47, 51000 Rijeka, Republic of Croatia

Name and address of site:
JADRAN-GALENSKI LABORATORIJ d.d. (abbreviated company name: JGL d.d.)
Osječka 47, 51000 Rijeka, Republic of Croatia

☒ Medicinal products *Human Medicinal Product*

Authorised operations *Authorised operations* ☐ Manufacturing (PART I) *Manufacturing Operations (according to part 1)* ☒ Importation (PART 2) *Importation of Medicinal Products (according to part 2)*

PART 2. IMPORTATION OF MEDICINAL PRODUCTS *Part 2 – IMPORTATION OF MEDICINAL PRODUCTS*	
2.3	**Other importation activities** ***Other importation activities***
	2.3.1 Location of physical importation of medicinal product *Site of physical importation*
	2.3.2 Importation of intermediates for further manufacture *Importation of intermediate which undergoes further processing*

Limitation or explanations related to enlisted for importation:
Any restriction or clarification remarks related to scope of these Importation operations:

Activities of storage and distribution of medicinal products are performed on above mentioned manufacturing site.
Activities of storage and distribution of medicinal products are performed on above mentioned manufacturing site

(Seal: round shape -
Republic of Croatia
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Zagreb
Agency for Medicinal
Products and Medical
Devices)

I, Public notary from Rijeka, Korzo 4,
confirm that this is a copy of original document:

DECISION,
issued by: Republic of Croatia, Agency for medicinal products and medical devices;

Class: UP/I-530-01/13-03/09;
Docket No.: 381-13-04/151-13-05,
In Zagreb, 19 December 2013,
with addendum 1A, 1B and 1C;

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NUMBER: OV-297/14
In Rijeka, 21 January 2014

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NOTARY PUBLIC

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PUBLIC NOTARY ASSISTANT)

(Seal: round shape - Republic of Croatia I

Public Notary)

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Public Notary)

I, Permanent Court Interpreter for the English language, as appointed by the President of the Country Court in Rijeka Decree No. 4-Su-472/2013 of 19 June 2013 do hereby certify that the above translation is a faithful and complete translation of the original document written in the Croatian language. OV-07/14, 21 January 2014

REPUBLIKA HRVATSKA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE

REPUBLIC OF CROATIA
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OIB 37926884937

Klasa: UP/I-530-01/13-03/09
Ur. broj: 381-13-04/151-13-05

U Zagrebu, 19. prosinca 2013. godine

Dostaviti:
1.
2. Pismohrana-ovdje

REPUBLIKA HRVATSKA - AGENCIJA ZA LIJEKOVE - MEĐIMURSKE PROIZVODE
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2

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