

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH

Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
INSPECTION OPERATIONS SECTOR
Department for the Inspection of Medicines
and Medical
Devices and Psychoactive Controlled
Substances and Precursors
Number: 515-04-00893/2017-11
Date: October 18th, 2017
Novi Beograd, Omladinskih brigada Street No. 1
Tel: +381 11 311 16 47

"SB TRADE" d.o.o.
Belgrade
Bitoljska Street No. 20

Report on determining the compliance of the production of active substances with the Guidelines of Good Manufacturing Practises Part II – Basic requirements for the production of active substances used in medicine manufacturing ("Official Gazette of the Republic of Serbia", number 86/10).

Pursuant to Articles 112 and 213, Paragraph 1, Item 1 of the Law on Medicines and Medical Devices ("Official Gazette of the Republic of Serbia", No. 30/10 and 107/12) inspectors for medicines and medical devices performed monitoring 27th and 28th of February 2017 and September 21st, 2017 at the production site of active substances, in Belgrade, Kružni put Street No. 26, at the request of the Company for manufacture, commerce and services **"SB TRADE" doo** Belgrade, in Belgrade, Bitoljska Street No. 20, with the purpose of determining the compliance of the production of active substances used in medicine manufacturing with the Guidelines of Good Manufacturing Practises Part II – Basic requirements for the production of active substances used in medicine manufacturing ("Official Gazette of the Republic of Serbia", number 86/10).

The main focus of determination of the compliance of the production of active substances with the Guidelines of Good manufacturing practises Part II – Basic requirements for the production of active substances used in medicine manufacturing ("Official Gazette of the Republic of Serbia", number 86/10) was on repacking of the active substances, their re-labelling and quality control. Inspectors made a Minutes/Report number 515-04-00893/2017-11 based on their monitoring procedure.

Based on the assessment of the inspectors of determined facts, it is noted that there were no critical incompliances in the production of active substances used in medicine manufacturing, therefore we hereby render the following



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Confirmation on compliance

of the production of active substances used in the medicines manufacturing with the Guidelines of Good Manufacturing Practises Part II – Basic requirements in production of active substances used in the medicines manufacturing (“Official Gazette of the Republic of Serbia”, number 86/10) at the production site – “SB TRADE” doo Belgrade, in Belgrade, Kružni put Street No. 26, whereas the production of active substances includes repacking of the active substances, their re-labelling and quality control.

Copy to:

1. “SB TRADE” d.o.o. Belgrade,
Bitoljska Street No. 20
2. Archives office

Inspectors for medicines

and medical devices

(signed)

Vesna Veljković, Magister of Pharmacy

(signed)

Tijana Radojičić, Magister of Pharmacy

(round seal: Coat of Arms, REPUBLIC OF SERBIA, MINISTRY OF HEALTH, BELGRADE)

END OF TRANSLATION

I, the undersigned sworn-in court translator, according to the Decision of the Ministry of Justice of the Republic of Serbia, no. 760-06-197/2002-04 from 02.10.2002 certify hereby that this translation into English is fully true to the original text written in Serbian language.

*Belgrade, October 23rd, 2017
Diary No.: 927/2017*

*Milena Kovačević, B.A.,
Sworn-In Court Translator for English,
Swedish and Slovenian*

