



REPUBLIC OF NORTH MACEDONIA
AGENCY FOR MEDICINES AND MEDICAL
DEVICES



Certificate No: 18-3280/4
Date 25.04.2019

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 AGENCY FOR MEDICINES AND MEDICAL DEVICES OF THE REPUBLIC OF NORTH MACEDONIA confirms the following:

The manufacturer **Pharmaceutical Industry INTER- EVROGENEKS DOOEL**

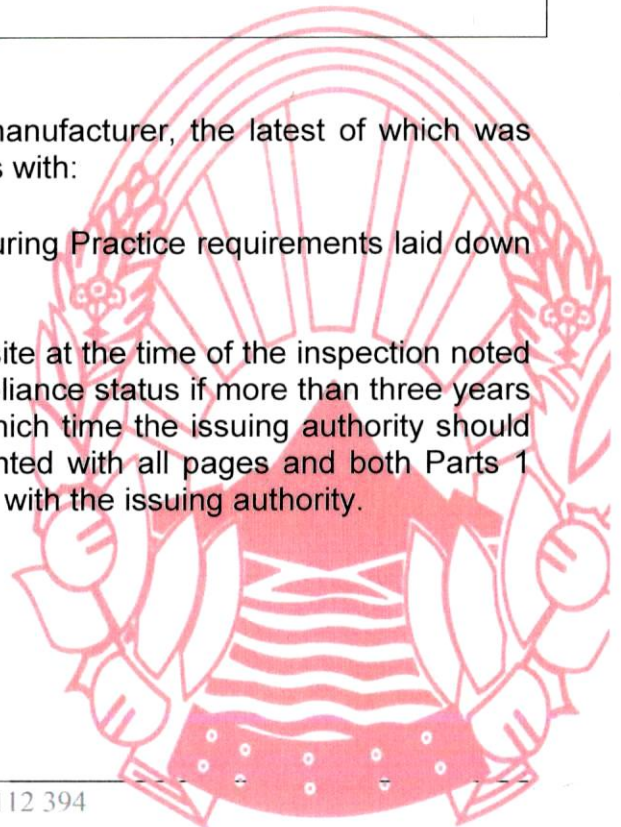
Site address: Str.Goce Delcev No.12, 2434 Novo Selo, R.of Macedonia

Has been inspected under the national inspection programme in connection with manufacturing authorization and in accordance with Art.40 of Directive 2001/83/EC transposed in the national legislation Law on medicines and medical devices (Official gazette of the RM No. 106/07,88/2010, 36/11, 53/11, 136/11, 11/12, 147/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, 113/18 и 245/18).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 24.04.2019 it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

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. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.





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Part 2

HUMAN MEDICINAL PRODUCTS

1. Manufacturing operations

1.1	Non-sterile products
1.1.1	Manufacturing of traditional herbal products and border products in solid and liquid dosage forms
1.2	Packaging
1.2.1	Primary packaging of traditional herbal products and border products in solid and liquid dosage forms
1.2.2	Secondary packaging
1.3	Batch certification

Agency for medicines and medical devices
Director,
Doc.d-r Qahil Ibrahim



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Skopje

