



REPUBLIC OF MACEDONIA
AGENCY FOR MEDICINES AND MEDICAL
DEVICES



Certificate No: 18-8963/3

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(1) and article 111(5) of Directive 2001/83/EC

The competent authority AGENCY FOR MEDICINES AND MEDICAL DEVICES OF THE REPUBLIC OF MACEDONIA confirms the following:

The manufacturer **NYSK HOLDING DOOEL Skopje**
Company for manufacturing, trade and services

Site address: Bul. „Boris Trajkovski “ 73, 1000 Skopje

Quality control address:

Chemical/Physical : NYSK HOLDING DOOEL Skopje Bul. „Boris Trajkovski “ 73, 1000 Skopje
Microbiological testing : PHI INSTITUT OF PUBLIC HEALTH of the Republic of Macedonia, ul.50
Division No.6, Skopje

Has been inspected under the national inspection programme in connection with manufacturing authorization and in accordance with Art.111 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 и 113/18) and Law on narcotic drugs and psychotropic substances (Official gazette of the RM No. 103/08, 124/10, 164/13, 149/15, 37/16 и 193/17).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 07.11.2018 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 all three parts: Parts 1 and 2.

The authenticity of this certificate may be verified with the issuing authority.



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Part 2

1. Manufacturing operations

1.2	Production of Cannabis extracts
	1.2.1 Extraction of substance from plant source (extraction from dried Cannabis floss or another herbal part)
1.2.1	Primary packaging
1.3	Production of products which contain extract of cannabis in pharmaceutical dosage forms
	1.2.1 Solutions
	1.2.1.1 Primary packaging
	1.2.1.2 Secondary packaging
	1.2.1.3 Batch certification
1.4	Quality control testing
	3.6.1 Chemical/Physical
	3.6.2 Microbiological: non-sterility Institut of Public health of the Republic of Macedonia

Agency for medicines and medical devices
Director,

Doc. Dr. Qahil Ibraimi



Certificate No: 18-8963/3

Date: 15-11-2018

Skopje