MALMED

AGENCY FOR MEDICINES AND MEDICAL DEVICES
Skopje

No. 18-540/3
Date: 31-03-2020

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) and 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

OAZA ALKALOIDI DOO ŠTIP
Company for production and trade

Site address: Gladno Pole, Tarinci , Karbinci
Company headquarter : Str.Toso Arsov 32 Štip

Has been inspected under the national inspection program in connection with manufacturing authorization No.19-58/6 dated 09.08.2017 and No.19-50/2 dated 07.02.2018 in accordance with 111(5) and 111(5) 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, 245/18) and Law on control of narcotic drugs and psychotropic substances (Official gazette of the RM No.103/08, 124/10,164/13, 149/15, 37/16 and 193/17).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 23-24.12.2019 it is considered thatit 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.

Agency for medicines and medical devices Skopje
street St. Cyril and Methodius, no. 54, first floor
1000, Skopje, Republic of North Macedonia
+389 2 5112-394
www.malmed.gov.mk

Part 2

ACTIVE SUBSTANCES

3. Manufacturing operations- ACTIVE SUBSTANCE CANNABIS	
3.2	Extraction of Active Substances from Natural Sources
	3.2.7 Other: Cultivation, cutting, drying and packaging of plant material cannabis for medical use
3.5	Finishing steps
	3.5.2 Primary packing
	3.5.3 Secondary packing

Agency for medicines and medical devices
Director,
M-r pharm. Visara Riza