

Release certificate

Product: Cannabis flos, variety Bediol (hemp flowers), granulated

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: ca. 6.3% cannabidiol: ca. 8%

Dosage form: flowers

Laboratory:

Package size: 5 grams in container, 400 grams in bags

23J23FB23L06 Batch: Order numbers: containers: 385602 385604 bags:

Grower/drier: Bedrocan Nederland B.V.

harvest date/period: P.O. Box 2009 23 October 2023

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. dose: irradiation: Soevereinstraat 2 06 December 2023 ≥ 10,0 kGy NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

Venkelbaan 101 14 December 2023 - 15 December 2023

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V.

Heembadweg 5 Analysis number: 46764 NL-9561 CZ Ter Apel Report date: 05 December 2023

1.

Microbiology of end product in container

General analysis

Analysis number: 47519

Report date: 11 January 2024 Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

Characters	Method Monograph	Specification Odour characteristic for Cannabis flower. Does not contain stalks that are longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm	Result conform
Macroscopic botanical characters	Visual	Brown, green granulates of flowers of about 4 to 6 mm in diameter	conform
Microscopic botanical characters	Monograph	Gland hairs are mainly observed	conform
Thin-layer chromatography	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	conform
Foreign material	Visual	Free from insects and other vermin	conform

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference 23J23FB23L06				
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10²	cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	<10 ¹	cfu/gram
S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria		Absent (1 gram)	conf	orm
Aflatoxins	Monograph			
Aflatoxin B ₁	Worlograph	≤ 2 µg/kg	-20	μg/kg
Sum of aflatoxins B ₁ , B ₂ ,		≥ 2 μg/kg ≤ 4 μg/kg		μg/kg
G_1 and G_2		2 + μg/kg	V 4.0	ружу
Pesticides	Ph. Eur. (current ed.)			
Tostorado	2.8.13	≤ Limits Ph. Eur. 2.8.13*	conf	orm
Heavy metals	Ph. Eur. (current ed.)			
Lead	2.4.27, 2.2.58	max. 20.0 ppm	< 5	ppm
Cadmium		max. 0.5 ppm	< 0.125	ppm
Mercury		max. 0.5 ppm	< 0.125	ppm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	7.1	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.4	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.7	%
Related substances (HPLC)	Ph. Eur. (current ed.)			
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	0.1	%
Content of container Expiry date	BMC-SWV 455	5 gram	± 5.15 31 Oct.	

^{*}The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl and tetradifon. The limit of detection is increased for fenpropathrin to 0.1 mg/kg and azinphos-ethyl to 1 mg/kg.

I hereby certify that the above information is authentic and accurate. This batch of product has been cultivated and manufactured, including packaging and quality control at the above mentioned sites in full compliance with the GAP requirements as published in the Dutch State Gazette (Staatscourant) as the annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, and with the specifications as stated in this document. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GAP and GMP.

The Hague, the Netherlands, 05 February 2024

K. Amponsah / R.V. Goormachtigh QA, Office of Medicinal Cannabis