

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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

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

Batch: 23G10FB23I20

Order numbers: containers: 385266 to 385267

bags: 385269

Grower/drier: Bedrocan Nederland B.V. harvest date/period:

P.O. Box 2009 10 July 2023

NL- 9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 20 September 2023 \geq 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

Venkelbaan 101 09 October 2023 – 11 October 2023

NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V. 1. General analysis

Heembadweg 5 Analysis number: 45108

NL-9561 CZ Ter Apel Report date: 21 September 2023

OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

Microbiology of end product in container

Analysis number: 46410

Report date: 02 November 2023

Method Specification Result
Characters Monograph Odour characteristic for conform
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

Identification

Testing method:

Macroscopic botanical Visual Brown, green granulates

characters of flowers of about 4 to 6 conform

mm in diameter

Microscopic botanical Monograph Gland hairs are mainly conform

characters observed

Thin-layer chromatography Ph. Eur. (current ed.) Comparable with conform

2.2.27, Monograph reference

Foreign material Visual Free from insects and conform

other vermin

P.O. Box 16114 NL-2500 BC THE HAGUE The Netherlands

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Page 2

Our reference 23G10FB23I20				
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	<10¹	cfu/gram
S. aureus, P. aeruginosa,				
bile-tolerant gram- negative bacteria		Absent (1 gram)	conform	
Aflatoxins	Monograph			
Aflatoxin B ₁		≤ 2 µg/kg	< 2.0	µg/kg
Sum of aflatoxins B1, B2,		≤ 4 µg/kg	< 4.0	μg/kg
G_1 and G_2				
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	conform	
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 %	8.8	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.0	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.3	%
Related substances (HPLC)	Ph. Eur. (current ed.)			
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	< 0.1	%
Content of container	BMC-SWV 455	5 gram	± 5.15	gram
Expiry date			31 Aug.	2024

^{*}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, 14 November 2023

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