

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

Grower/drier:

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

23J09FB23K22 Batch:

Order numbers: containers: 385548 to 385549 and 385535

> bags: not applicable

Bedrocan Nederland B.V.

P.O. Box 2009 09 October 2023 NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 22 November 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

> 12 December 2023 - 13 December 2023 Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

Heembadweg 5 NL-9561 CZ Ter Apel General analysis

harvest date/period:

Analysis number: 46633

Report date: 28 November 2023

Microbiology of end product in container

Analysis number: 47517 Report date: 11 January 2024

OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021 Testing method:

	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			
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	

Ministry of Health, Welfare and Sport

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Our reference 23J09FB23K22				
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ²	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)	confo	orm
Aflatoxins	Monograph			
Aflatoxin B ₁		≤ 2 µg/kg	< 2.0	µg/kg
Sum of aflatoxins B_1 , B_2 , G_1 and G_2		≤ 4 µg/kg	< 4.0	µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	confo	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 %	6.6	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.2	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.4	%
Related substances (HPLC)	Ph. Eur. (current ed.)			

≤ 1.0 %

5 gram

0.1 %

± 5.15 gram

31 Oct. 2024

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

Cannabinol (CBN, total 2.2.29, Monograph

BMC-SWV 455

equivalent) Content of container

Expiry date

6. Approch

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

^{*}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.