

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: 22J03FB23B15

Order numbers: containers: 384144 and 384145

bags: 384147

Grower/drier: Bedrocan Nederland B.V. harvest date/period: P.O. Box 2009 03 October 2022

NL- 9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 15 February 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron B.V. date

Venkelbaan 101 14 March 2023 – 20 March 2023

NL-2908 KE Capelle a/d IJssel

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

Heembadweg 5 Analysis number: 40100 NL-9561 CZ Ter Apel Report date: 15 November 2022

2. Microbiology of end product in container

Analysis number: 42914 Report date: 30 March 2023

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

	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 mm in diameter	conform
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	

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Microbial contamination	Ph. Eur. (current ed.)					
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/grai	m	< 10²	cfu/gram	
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/grai	m	< 10¹	cfu/gram	
S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria		Absent (1 gra	m)	conf	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*		conf	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	%	7.8	%	
Assay (HPLC)	Ph. Eur. (current ed.)					
Tetrahydrocannabinol	2.2.29, Monograph	6.3 % [5.	.0 – 7.6]	6.1	%	
(THC, total equivalent)						
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 Expiry date	BMC-SWV 360	5	gram	± 5.15 29 Feb.	0	

^{*}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.

Hague, the Netherlands, 04 April 2023

Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis