

Release certificate

Product: Cannabis flos, variety Bedrocan (hemp flowers)

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: ca. 22% cannabidiol: < 1.0%

Dosage form: flowers

Grower/drier:

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

Batch: 22J24EY23B08

Order numbers: containers: 384117 to 384121

> bags: 384122

Bedrocan Nederland B.V. harvest date/period: P.O. Box 2009 24 October 2022

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 08 February 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: date: Fagron B.V.

> 09 March 2023 - 15 March 2023 Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

1. Heembadweg 5 NL-9561 CZ Ter Apel

Analysis number: 40512 Report date: 05 December 2022

2. Microbiology of end product in container

Analysis number: 42915 Report date: 30 March 2023

General analysis

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

	Method	Specification	Result
Characters	Monograph	Odour characteristic for	conform
		Cannabis flower. Leaves	
		shoot out no more than	
		20% of the length of the	
		flower and stalks are	
		mostly cut off directly	
		under the bottom site of	
		the flowers	
Identification			
Macroscopic botanical	Visual	Brown, green clustered	
characters		flowers of about 1.5 to	conform
		3.0 cm length	
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	

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference 22J24EY23B08

22J24EY23B08				
Foreign material	Visual	Free from insects and other vermin	confo	orm
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		≤10¹ cfu/gram	< 10 ¹	cfu/gram
yeasts/moulds count				
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram- negative bacteria		Absent (1 gram)	confo	rm
Aflatoxins	Monograph			
Aflatoxin B ₁	Worldgraph	≤ 2 µg/kg	< 2.0	ua/ka
Sum of aflatoxins B ₁ , B ₂ ,		≤ 4 μg/kg	< 4.0	
G_1 and G_2		_ + μg/kg	V 4.0	Marka
Pesticides	Ph. Eur. (current ed.)			
i esticides	2.8.13	≤ Limits Ph. Eur. 2.8.13*	confo	rm
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.)	≤ 10.0 %	8.1	%
	2.2.32			
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol	2.2.29, Monograph	22 % [17.6 – 26.4]	20.7	%
(THC, total equivalent)				
Cannabidiol (CBD, total equivalent)		<1.0 %	0.1	%
Related substances (HPLC)	Ph. Eur. (current ed.)			
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	< 0.1	%
Content of container	BMC-SWV 360	5 gram	± 5.14	aram
Expiry date	2.7.0 011 1 000	o grain	29 Feb.	-
Expiry date			20100.	2027

^{*}The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxon-methyl 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, 04 April 2023

Dr. M. J. van de Velde

Head, Office of Medicinal Cannabis