

## Release certificate

Product: Cannabis flos, variety Bedrocan (hemp flowers)

Country: to be sold on the pharmaceutical market

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

Dosage form: flowers

Grower/drier:

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

Batch: 23B27EY23E24

Order numbers: containers: 384753 to 384760 and 384912

bags: 384762 Bedrocan Nederland B.V.

harvest date/period: P.O. Box 2009 27 February 2023

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. dose: date: irradiation: Soevereinstraat 2 24 May 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

> Venkelbaan 101 30 June 2023 - 07 July 2023

NL-2908 KE Capelle a/d IJssel

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

> Heembadweg 5 Analysis number: 42843 NL-9561 CZ Ter Apel Report date: 13 April 2023

> > Microbiology of end product in container

Analysis number: 44685 Report date: 18 July 2023

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 23B27EY23E24

2302/6123624					
Foreign material	Visual	Free from insects and other vermin		conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10²	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gra	m	< 10¹	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gram)		conform	
Aflatoxins	Monograph				
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg		< 2.0	μg/kg
Sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> ,		≤ 4 µg/kg		< 4.0	μg/kg
$G_1$ and $G_2$					
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur.	r. 2.8.13* conform		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	%	8.2	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	20.7	%
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 455	5	gram	± 5.15	gram
Expiry date				31 May	_

<sup>\*</sup>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, 25 July 2023

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