

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Release certificate

Cannabis flos, variety Bedrocan (hemp flowers) Product:

Country: to be sold on the pharmaceutical market

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

Dosage form: flowers

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

Batch: 22K21EY23C08

Order numbers: containers: 384270 to 384276

> 384279 bags:

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

P.O. Box 2009 21 November 2022

NL-9640 CA Veendam

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

NL-4879 NN Etten-Leur

Packager: Fagron B.V. date:

> Venkelbaan 101 30 March 2023 - 06 April 2023

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

General analysis Analysis number: 40895 Heembadweg 5

NL-9561 CZ Ter Apel Report date: 29 December 2022

Microbiology of end product in container

Analysis number: 43358 Report date: 20 April 2023

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

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

flowers of about 1.5 to conform characters

3.0 cm length

Gland hairs are mainly conform Microscopic botanical Monograph

characters observed

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

2.2.27, Monograph reference

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Our reference

22K21EY23C08					
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/gram		< 10 ²	cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram		< 10¹	cfu/gram
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin B_1		≤ 2 µg/kg			µg/kg
Sum of aflatoxins B_1 , B_2 ,		≤ 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		< 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 (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	21.5	%
Cannabidiol (CBD, total equivalent)		<1.0	%	0.1	%
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
equivalent)	z.z.zo, Wonograph	_ 1.0	70	7 0.1	70
Content of container	BMC-SWV 360	5	gram	± 5.15	gram
Expiry date				31 March	2024

^{*}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 April 2023

Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis