

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

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

23D10EY23G19 Batch:

containers: 385006 to 385015 Order numbers:

> bags: 385017

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

> P.O. Box 2009 10 April 2023

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 19 July 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

> Venkelbaan 101 08 August 2023 - 25 August 2023

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

General analysis 1. Analysis number: 43647 Heembadweg 5 Report date: 22 May 2023 NL-9561 CZ Ter Apel

Microbiology of end product in container

Analysis number: 45376

Report date: 04 September 2023

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

Characters	Method Monograph	Specification Odour characteristic for 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	Result conform	
Identification				
Macroscopic botanical	Visual	Brown, green clustered		
characters		flowers of about 1.5 to 3.0 cm length	conform	
Microscopic botanical characters	Monograph	Gland hairs are mainly observed	conform	
Thin-layer chromatography	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	conform	

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Our reference 23D10EY23G19

23D10EY23G	19					
Foreign mate	erial	Visual	Free from insects and other vermin		conform	
Microbial cor	ntamination	Ph. Eur. (current ed.)				
Total aerob count (TAN	ic microbial IC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10²	cfu/gram
Total comb	ined		≤10¹ cfu/gra	m	< 10 ¹	cfu/gram
yeasts/mou (TYMC)						
S. aureus, F	P. aeruginosa,					
bile-toleran negative ba	~		Absent (1 gra	m)	conf	orm
Aflatoxins		Monograph				
Aflatoxin E	31		≤ 2 µg/kg		< 2.0	μg/kg
Sum of affa G_1 and G_2	atoxins B ₁ , B ₂ ,		≤ 4 µg/kg		< 4.0	µg/kg
Pesticides		Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2	2.8.13*	conf	orm
Heavy metals	6	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 dryir	ng	Ph. Eur. (current ed.) 2.2.32	≤ 10.0	%	8.8	%
Assay (HPLC))	Ph. Eur. (current ed.)				
Tetrahydro	cannabinol	2.2.29, Monograph	22 % [17.6	6 - 26.4	20.2	%
(THC, total	equivalent)					
Cannabidio equivalent)	ol (CBD, total		<1.0	%	0.2	%
Related subs	tances (HPLC)	Ph. Eur. (current ed.)				
Cannabino equivalent)	l (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
Content of co	ontainer	BMC-SWV 455	5	gram	± 5.15	gram
Expiry date					31 July	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, 12 September 2023

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