

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

Package size:

5 grams in container, 400 grams in bags

Batch:

23D24EY23I27

Order numbers:

containers: 385283 to 385291

bags:

385293

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 24 April 2023

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

27 September 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

09 October 2023 - 26 October 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

Venkelbaan 101

NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 43880 Report date: 12 June 2023

Microbiology of end product in container

Analysis number: 46411

Report date: 02 November 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 characters	Visual	Brown, green clustered	
			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	

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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23D24EY23I27					
Foreign material	Visual	Free from insect	an arminen	confe	orm
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/grar	m	< 10 ²	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)	confe	orm
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	
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	2.8.13*	conf	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	%	8.1	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	19.3	%
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 Expiry date	BMC-SWV 455	5	gram	± 5.14 31 Aug.	

^{*}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, 21 December 2023

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