

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:

23D03EY23F21

Order numbers:

containers: 384881 to 384890

bags:

384993

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

date:

dose:

Gamma

Synergy Health Ede B.V.

21 June 2023

03 April 2023

≥ 10,0 kGy

irradiation:

Soevereinstraat 2

Packager:

NL-4879 NN Etten-Leur Fagron Nederland B.V.

date:

Venkelbaan 101 NL-2908 KE Capelle a/d IJssel

18 July 2023 - 25 July 2023

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

1. General analysis

Analysis number: 43508 Report date: 16 May 2023

NL-9561 CZ Ter Apel

2. Microbiology of end product in container

Analysis number: 44910 Report date: 04 August 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	

Telefax +31 70 340 7426

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

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Foreign material	Visual	Free from insects a other vermin	nd c	conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	<	33 cfu/gram	
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram		< 7 cfu/gram	
S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria		Absent (1 gram)	С	onform	
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		2.0 μg/kg	
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. 2.8.	.13* c	conform	
Heavy metals	Ph. Eur. (current ed.)				
Lead	2.4.27, 2.2.58	max. 20.0 pp	om	< 5 ppm	
Cadmium		max. 0.5 pp	om < 0.1	125 ppm	
Mercury		max. 0.5 pp	om < 0.1	125 ppm	
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %		7.7 %	
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 –	26.4] 2	1.0 %	
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 gr	am ± 5	.15 gram	
Expiry date			30 Ju	une 2024	

^{*}The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl 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.

2023 The Hague, the Netherlands, 10 August 2024

R.V. Goormachtigh / B. van Beek

QA, Office of Medicinal Cannabis