

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:

23A02EY23D12

Order numbers:

containers: 384545 to 384551

bags:

384553

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 02 January 2023

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

12 April 2023

≥ 10,0 kGy

Soevereinstraat 2

NL-4879 NN Etten-Leur

date:

Packager: Fagron B.V.

Venkelbaan 101

05 May 2023 - 15 May 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

General analysis 1.

Heembadweg 5 NL-9561 CZ Ter Apel

Analysis number: 41712 Report date: 13 Feb. 2023

Microbiology of end product in container

Analysis number: 43948 Report date: 01 June 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	conform
characters		flowers of about 1.5 to	
		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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Our reference 23A02EY23D12

23A02L123D12					
Foreign material	Visual	Free from insect other vermi		conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 ²	cfu/gram
count (TAMC)					
Total combined		≤10¹ cfu/gra	m	< 10 ¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gra	m)	confe	orm
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins B_1 , B_2 ,		≤ 4 µg/kg		< 4.0	
G₁ and G₂		100			
Pesticides	Ph. Eur. (current ed.)				
	2.8.13	≤ Limits Ph. Eur.	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.)	≤ 10.0	%	8.0	%
	2.2.32				
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	22 % [17.6	6 – 26.4]	20.1	%
(THC, total equivalent)					
Cannabidiol (CBD, total		<1.0	%	0.1	%
equivalent)					
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
equivalent)		2 1.0	, ,		, -
Content of container	BMC-SWV 360	5	gram	± 5.15	aram
Expiry date	51110 0111 000	3	grain	30 Apr.	= -
Explity date				oo Apr.	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, 08 June 2023

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