

Office of Medicinal Cannabis



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:

22J03EY23A04

Order numbers:

containers: 384019

bags:

Not applicable

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

03 October 2022

Gamma

Synergy Health Ede B.V.

date:

Soevereinstraat 2

04 January 2023

≥ 10,0 kGy

dose:

Daniela

NL-4879 NN Etten-Leur

Packager:

irradiation:

Fagron B.V.

date:

Venkelbaan 101

21 February 2023

Laboratory:

NL-2908 KE Capelle a/d IJssel Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

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1. General analysis

Analysis number: 40101

Report date: 15 November 2022

Microbiology of end product in container

Analysis number: 42422 Report date: 07 March 2023

Testing method:

OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

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	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	

Ministry of Health, Welfare and Sport

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Our reference 22J03EY23A04

22J03EY23A04				
Foreign material	Visual	Free from insects and other vermin	conf	orm
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		≤10¹ cfu/gram	< 10 ¹	cfu/gram
yeasts/moulds count				
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram-		Absent (1 gram)	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	μg/kg
G_1 and G_2				
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.) 2.2.32	≤ 10.0 %	8.4	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol	2.2.29, Monograph	22 % [17.6 – 26.4]	20.6	%
(THC, total equivalent)				
Cannabidiol (CBD, total		<1.0 %	0.1	%
equivalent)				
Related substances (HPLC)	Ph. Eur. (current ed.)			
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	< 0.1	%
Content of container	BMC-SWV 360	5 gram	± 5.14	_
Expiry date			31 Dec.	2023

^{*}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, 10 March 2023

Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis