

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:

22K28EY23C15

Order numbers:

containers: 384338 to 384344

bags:

384346

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

28 November 2022

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation: Soevereinstraat 2

NL-4879 NN Etten-Leur

15 March 2023

≥ 10,0 kGy

Result

Packager: Fagron B.V.

Venkelbaan 101

date:

06 April 2023 - 13 April 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

Method

General analysis

Analysis number: 41083 Report date: 03 January 2023

Microbiology of end product in container

Analysis number: 43455 Report date: 01 May 2023

Testing method:

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

Specification

Characters	Monograph	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	conform
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	

The Netherlands

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 22K28EY23C15

22K28EY23C15			
Foreign material	Visual	Free from insects and other vermin	conform
Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 <sup>2</sup> cfu/gram
Total combined		≤10¹ cfu/gram	< 10¹ cfu/gram
yeasts/moulds count (TYMC)			
S. aureus, P. aeruginosa,			
bile-tolerant gram-		Absent (1 gram)	conform
negative bacteria			
Aflatoxins	Monograph		
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg	< 2.0 µg/kg
Sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> ,		≤ 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*	conform
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 %	6.7 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 – 26.4]	23.7 %
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 360	5 gram	± 5.15 gram
Expiry date	23 3 333	o gram	31 March 2024

<sup>\*</sup>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 May 2023

K. Amponsah / S. Vos- de Schipper

QA, Office of Medicinal Cannabis