

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

## Release certificate

Product:

Cannabis flos, variety Bedrolite (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: < 1.0%

cannabidiol: ca. 7.5%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

22L26FR23C22

Order numbers:

containers: 384399 to 384400

bags:

384402

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 26 December 2022

NL-9640 CA Veendam

Gamma

date:

dose:

irradiation:

Synergy Health Ede B.V.

22 March 2023

≥ 10,0 kGy

Soevereinstraat 2 NL-4879 NN Etten-Leur

Packager:

Fagron B.V.

date:

Venkelbaan 101

12 April 2023 - 14 April 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

General analysis 1.

Analysis number: 41620 Report date: 06 February 2023

Microbiology of end product in container

Analysis number: 43643 Report date: 09 May 2023

Testing method:

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

Characters	<b>Method</b> Monograph	Specification Odour characteristic for Cannabis flower. Does not contain stalks that are longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm	Result conform
Identification			
Macroscopic botanical	Visual	Brown, green granulates	
characters		of flowers of about 4 to 6 mm in diameter	conform
Microscopic botanical	Monograph	Gland hairs are mainly	conform
characters		observed	
Thin-layer chromatography	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	conform
Foreign material	Visual	Free from insects and other vermin	conform

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Our reference					
22L26FR23C22	DI 5 /				
Microbial contamination	Ph. Eur. (current ed.)	1402 6 /		1103	
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra			cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gra	m	≤10¹	cfu/gram
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gra	ım)	conf	orm
negative bacteria		Abscit (1 gic		COIII	OTTT
Aflatoxins	Monograph				
Aflatoxin B <sub>1</sub>	Wollograph	≤ 2 µg/kg		< 2.0	μg/kg
Sum of aflatoxins $B_1$ , $B_2$ ,		≤ 4 μg/kg			μg/kg
$G_1$ and $G_2$					F-33
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	%	7.4	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	< 1.0	%	0.3	%
Cannabidiol (CBD, total equivalent)		7.5 % [6	.0 – 9.0]	7.7	%
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	gram

<sup>\*</sup>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.

31 March 2024

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, 12 May 2023

Expiry date

6 Appoisel K. Amponsah / S. Vos- de Schipper QA, Office of Medicinal Cannabis