

## 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:

23K20FR24A03

Order numbers:

containers: 385997

bags:

385998

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period: 20 Nov 2023

P.O. Box 2009

NL-9640 CA Veendam

date:

dose:

Gamma

Synergy Health Ede B.V.

03 Jan 2024

≥ 10,0 kGy

irradiation: Soevereinstraat 2

NL-4879 NN Etten-Leur

date:

Fagron Nederland B.V. Packager:

04 Jun 2024

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 47195 Report date: 03 Jan 2024

2. Microbiology of end product in container

> Analysis number: 49617 Report date: 26 Jun 2024

Testing method:

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

	Method	Specification	Result
Characters	Monograph	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	Conform
Identification			
Macroscopic botanical	Visual	Brown, green granulates	
characters		of flowers of about 4 to 6 mm in diameter	Conform
Microscopic botanical characters	Monograph	Gland hairs are mainly observed	Conform
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

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference

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Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram	< 10² cfu/gram
count (TAMC)			
Total combined		≤10¹ cfu/gram	< 10 <sup>1</sup> 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.)	≤ Limits Ph. Eur. 2.8.13*	Conform
	2.8.13	≤ Limits Ph. Eur. 2.8.13"	Contorm
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 %	7.6 %
	2.2.32		
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol	2.2.29, Monograph	< 1.0 %	0.3 %
(THC, total equivalent)			
Cannabidiol (CBD, total		7.5 % [6.0 – 9.0]	8.2 %
equivalent)			
Related substances (HPLC)	Ph. Eur. (current ed.)		
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
equivalent)			
Content of container	BMC-SWV 455	5 gram	± 5.11 gram
Expiry date			31 Oct. 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, 27 June 2024

M. Mennens / S. Vos- de Schipper QA, Office of Medicinal Cannabis