

## 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:

24K11FR24L04

Order numbers:

containers: 386936 to 386937

bags:

not applicable

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL- 9640 CA Veendam

11 Nov. 2024

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

04 Dec. 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

09 Jan.2025 – 13 Jan. 2025

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

Analysis number: 51407 Report date: 10 Dec. 2024

2. Microbiology of end product in container

Analysis number: 52130 Report date: 28 Jan. 2025

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
Macroscopic botanical characters	Visual	Brown, green granulates 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

The Netherlands

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

Page 2 Our reference

Our reference 24K11FR24L04

24K11FR24L04					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	ım	< 10 <sup>2</sup>	cfu/gram
Total combined		≤10¹ cfu/gra	ım	< 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.) 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	%	8.2	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	< 1.0	%	0.2	%
(THC, total equivalent)					
Cannabidiol (CBD, total equivalent)		7.5 % [6	5.0 – 9.0]	6.2	%
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	± 5.14	gram
Expiry date				31 Oct.	2025

<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, 30 January 2025

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