

## 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:

24J28EY24K27

Order numbers:

containers: 386910 to 386917

bags:

386919

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

28 Oct. 2024

Gamma Synergy Health Ede B.V. date:

dose:

Result

irradiation:

Soevereinstraat 2

27 Nov. 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

08 Jan. 2025 - 21 Jan. 2025

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

Method

General analysis 1.

Analysis number: 51217

Report date: 26 Nov. 2024

Microbiology of end product in container

Analysis number: 52071 Report date: 21 Jan 2025

Testing method:

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

Specification

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 Brown, green clustered Visual characters flowers of about 1.5 to conform 3.0 cm length Microscopic botanical Gland hairs are mainly Monograph conform characters observed

P.O. Box 16114 NL-2500 BC THE HAGUE The Netherlands

Telephone +31 70 340 5113 Telefax +31 70 340 7426

Address: Hoftoren Rijnstraat 50

Thin-layer chromatography Ph. Eur. (current ed.)

NL-2515 XP THE HAGUE The Netherlands

2.2.27, Monograph

All correspondence addressed to the postal address quoting date and reference of this letter.

Comparable with

reference

Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl

conform

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 24J28EY24K27

24J20E124N2/					
Foreign material	Visual	Free from insects and other vermin		conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram		< 10 <sup>2</sup>	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.)	t ed.) ≤ Limits Ph. Eur. 2.8.13*		conform	
	2.8.13				
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	%	8.4	%
	2.2.32				
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	22 % [17.6	6 - 26.4	21.4	%
(THC, total equivalent)					
Cannabidiol (CBD, total		<1.0	%	0.3	%
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 455	5	gram	± 5.15	gram
Expiry date				30 Sep.	2025
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<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