## Ministry of Health, Welfare and Sport

#### 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

bags:

Package size:

5 grams in container, 400 grams in bags

Batch:

24D15EY24E23

Order numbers:

containers: 386277

386278

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period: 15 Apr. 2024

P.O. Box 2009

Gamma

NL-9640 CA Veendam Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2 22 May 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101 31 July 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 48815 Report date: 14 May 2024

Microbiology of end product in container

Analysis number: 50181 Report date: 16 Aug. 2024

Testing method:

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

Characters	<b>Method</b> Monograph	Specification 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	<b>Result</b> Conform
Identification			Conform
Macroscopic botanical characters	Visual	Brown, green clustered flowers of about 1.5 to 3.0 cm length	
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

Telefax +31 70 340 7426

The Netherlands

### Ministry of Health, Welfare and Sport

### Office of Medicinal Cannabis

Page 2

Our reference 24D15EY24E23

240136124623			
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	<10² cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	<10 <sup>1</sup> cfu/gram
S. aureus, P. aeruginosa,			
bile-tolerant gram- negative bacteria		Absent (1 gram)	Conform
Aflatoxins	Monograph		
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg	< 2.0 µg/kg
Sum of aflatoxins $B_1$ , $B_2$ , $G_1$ and $G_2$		≤ 4 µg/kg	< 4.0 µg/kg
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 %	7.2 %
Assay (HPLC)	Ph. Eur. (current ed.)		

22 % [17.6 – 26.4]

<1.0 %

≤ 1.0 %

5 gram

22.9 %

0.3 %

< 0.1 %

± 5.15 gram

31 Mar. 2025

2.2.29, Monograph

2.2.29, Monograph

BMC-SWV 455

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, 20 August 2024

K. Amponsah / M. MennensQA, Office of Medicinal Cannabis

Tetrahydrocannabinol

(THC, total equivalent)

Cannabidiol (CBD, total

Cannabinol (CBN, total

Related substances (HPLC) Ph. Eur. (current ed.)

equivalent)

equivalent)
Content of container

Expiry date

<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.