

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:

24I30EY24J23

Order numbers:

containers: 386868 to 386876

386877 bags:

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

30 Sep 2024

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

23 Oct 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

03 Jan. 2025 - 17 Jan. 2025

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis

Analysis number: 50906 Report date: 28 Oct 2024

Microbiology of end product in container

Analysis number: 52069 Report date: 21 Jan 2025

Testing method:

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

Characters

Method Monograph Specification Odour characteristic for

Result 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

Visual

Brown, green clustered flowers of about 1.5 to

conform

characters

Monograph

Gland hairs are mainly

Microscopic botanical characters

observed

3.0 cm length

conform

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

Comparable with

2.2.27, Monograph

reference

conform

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The Netherlands

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

24I30EY24J23					
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		≤10¹ cfu/gram		< 101	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa, bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria		Abscitt (1 git	,	COIII	OIIII
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins B ₁ , B ₂ ,		≤ 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	%	7.8	
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	21.0	%
Cannabidiol (CBD, total equivalent)		<1.0	%	0.3	%
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
Content of container Expiry date	BMC-SWV 455	5	gram	± 5.15 31 Aug.	-

*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