

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:

23K27FR24A03

Order numbers:

containers: 386170

bags:

385999

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

27 Nov 2023

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

03 Jan 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

04 Jun 2024

Venkelbaan 101

Laboratory:

NL-2908 KE Capelle a/d IJssel Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 47196 Report date: 03 Jan 2024

Microbiology of end product in container

Analysis number: 49618

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

Conform

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

Identification

characters

Macroscopic botanical

Visual

Brown, green granulates

of flowers of about 4 to 6

Conform

mm in diameter

Microscopic botanical

characters

Monograph

Gland hairs are mainly

observed

Conform

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

Comparable with

Conform

2.2.27, Monograph

reference

Foreign material

Visual

Free from insects and

Conform

other vermin

The Netherlands

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

23K27FR24A03					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram		< 10 ²	cfu/gram
count (TAMC)					
Total combined		≤10¹ cfu/gram		< 10 ¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		Conform	
negative bacteria				i.	
Aflatoxins	Monograph				
Aflatoxin B₁		≤ 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.)	≤ Limits Ph. Eur. 2.8.13		Conform	
	2.8.13	= Ellillitä i II. Edi. i	2.0.10	COIII	Om
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	%
Assaul (HBLC)	Ph. Eur. (current ed.)				
Assay (HPLC)		< 1.0	0/	0.3	0/
Tetrahydrocannabinol	2.2.29, Monograph	< 1.0	/0	0.3	/0
(THC, total equivalent) Cannabidiol (CBD, total		7.5 % [6	0 0 01	7.6	0/
equivalent)		7.5 % [0	.0 – 3.0]	7.0	70
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				31Oct2024	

^{*}The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl 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