

Release certificate

Product:

Cannabis flos, variety Bedrolite (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: < 1.0%

Dosage form:

flowers

bags:

Package size:

5 grams in container, 400 grams in bags

Batch:

23K13FR23L20

Order numbers:

containers: 385622

385624

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 13 November 2023

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

20 December 2023

12 - 16 January 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

General analysis 1.

Analysis number: 47040

Report date: 19 December 2023

cannabidiol: ca. 7.5%

2. Microbiology of end product in container

Analysis number: 47809

Report date: 09 February 2024

Testing method:

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

Characters	Method 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

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

23K13FR23L20					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 ²	cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gra	m	< 10 ¹	cfu/gram
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gra	ım)	conf	orm
Aflatoxins	Monograph				
Aflatoxin B₁		≤ 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		orm	
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	%	7.5	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	< 1.0	%	0.3	%
Cannabidiol (CBD, total equivalent)		7.5 % [6	.0 – 9.0]	8.1	%
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	± 5.14 30 Nov.	_

^{*}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, 05 March 2024

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