

Ministry of Health, Welfare and Sport

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:

23J16FR23K22

Order numbers:

containers: 385551 to 385552

bags:

385550

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 16 October 2023

NL- 9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

22 November 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

13 December 2023 – 14 December 2023

Venkelbaan 101 NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis

Analysis number: 46632

Report date: 28 November 2023

2. Microbiology of end product in container

Analysis number: 47518 Report date: 11 January 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			
Macroscopic botanical	Visual	Brown, green granulates	
characters		of flowers of about 4 to 6	conform
		mm in diameter	
Microscopic botanical	Monograph	Gland hairs are mainly	conform
characters		observed	
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	

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Page

Our reference 23J16FR23K22

Microbial contamination

Total aerobic microbial count (TAMC) Total combined yeasts/moulds count

Ph. Eur. (current ed.)

Monograph

Ph. Eur. (current ed.)

Ph. Eur. (current ed.)

2.2.29, Monograph

Ph. Eur. (current ed.)

2.2.29, Monograph

BMC-SWV 455

2.2.32

≤102 cfu/gram

< 10² cfu/gram

< 5 ppm

≤101 cfu/gram < 101 cfu/gram

(TYMC)

S. aureus, P. aeruginosa, bile-tolerant gramnegative bacteria

Aflatoxins Aflatoxin B₁

Sum of aflatoxins B₁, B₂, G1 and G2 **Pesticides**

Ph. Eur. (current ed.) 2.8.13 Heavy metals Ph. Eur. (current ed.) Lead 2.4.27, 2.2.58

Cadmium Mercury Loss on drying

Assay (HPLC) Tetrahydrocannabinol (THC, total equivalent)

Cannabidiol (CBD, total equivalent) Related substances (HPLC)

Cannabinol (CBN, total equivalent)

Content of container Expiry date

2.6.12, 2.6.13

Absent (1 gram) conform

≤ 2 µg/kg $< 2.0 \mu g/kg$ $< 4.0 \mu g/kg$ ≤ 4 µg/kg

conform

≤ Limits Ph. Eur. 2.8.13*

max. 20.0 ppm < 0.125 ppm max. 0.5 ppm

max. 0.5 ppm < 0.125 ppm 7.6 % ≤ 10.0 %

< 1.0 %

0.3 %

7.5% [6.0 - 9.0]8.3 %

≤ 1.0 % < 0.1 %

5 gram ± 5.16 gram

31 Oct. 2024

*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 February 2024

K. Amponsah / R.V. Goormachtigh QA, Office of Medicinal Cannabis