

Release certificate

Product: Cannabis flos, variety Bediol (hemp flowers), granulated

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: ca. 6.3% cannabidiol: ca. 8%

Dosage form: flowers

Batch:

Package size: 5 grams in container, 400 grams in bags

23C06FB23G19

Order numbers: containers: 385019

bags: 385018

Grower/drier: Bedrocan Nederland B.V. harvest date/period: P.O. Box 2009 06 March 2023

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 19 July 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

Venkelbaan 101 11 August 2023 - 15 August 2023

NL-2908 KE Capelle a/d IJssel

General analysis Laboratory: Laboratorium Ofichem B.V. 1.

Heembadweg 5 Analysis number: 44206 NL-9561 CZ Ter Apel Report date: 04 July 2023

> Microbiology of end product in container 2.

> > Analysis number: 45377

Report date: 04 September 2023 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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Ministry of Health, Welfare and Sport



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Our reference
23C06FB23G19
Microbial contamination Ph. Eur. (current ed.)

Total aerobic microbial 2.6.12, 2.6.13

count (TAMC)

Total combined

yeasts/moulds count

< 10² cfu/gram

<101 cfu/gram

conform

≤10² cfu/gram

≤10¹ cfu/gram

Absent (1 gram)

negative bacteria
Aflatoxins Monograph

S. aureus, P. aeruginosa,

bile-tolerant gram-

Aflatoxin B_1 $\leq 2 \mu g/kg$ $< 2.0 \mu g/kg$ Sum of aflatoxins B_1, B_2 $\leq 4 \mu g/kg$ $< 4.0 \mu g/kg$

G₁ and G₂

(TYMC)

Pesticides Ph. Eur. (current ed.) \leq Limits Ph. Eur. 2.8.13* conform 2.8.13 Heavy metals Ph. Eur. (current ed.) \leq Limits Ph. Eur. 2.8.13* \leq Limits Ph. Eur. 2.8.13*

Cadmium max. 0.5 ppm < 0.125 ppm < 0.125 ppm max. 0.5 ppm < 0.125 ppm < 0.125

Assay (HPLC) 2.2.32
Ph. Eur. (current ed.)
Tetrahydrocannabinol 2.2.29, Monograph

Tetrahydrocannabinol2.2.29, Monograph6.3% [5.0-7.6]6.4%(THC, total equivalent)8.0% [6.4-9.6]8.7%

equivalent)

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 ± 5.15 gram Expiry date 31 July 2024

*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, 12 September 2023

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