

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: 23C20FR23G12
Order numbers: containers: 384963

bags: 384967

Grower/drier: Bedrocan Nederland B.V. harvest date/period: P.O. Box 2009 20 March 2023

NL- 9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 12 July 2023 \geq 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

Venkelbaan 101 04 August 2023

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. 1. General analysis

Heembadweg 5 Analysis number: 43265 NL-9561 CZ Ter Apel Report date: 01 May 2023

2. Microbiology of end product in container

Analysis number: 45199 Report date: 25 August 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 Gland hairs are mainly conform Monograph 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

The Netherlands

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference
23C20FR23G12
Microbial contamination Ph. Eur. (current ed.)
Total aerobic microbial 2.6.12, 2.6.13
count (TAMC)

 $\leq 10^2$ cfu/gram $< 10^2$ cfu/gram $\leq 10^1$ cfu/gram $< 10^1$ cfu/gram

yeasts/moulds count

Total combined

(TYMC)

S. aureus, P. aeruginosa,

bile-tolerant gram- Absent (1 gram) conform

negative bacteria

Aflatoxins Monograph

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

Pesticides Ph. Eur. (current ed.) \leq 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.) ≤ 10.0 % 8.3 % 2.2.32

Assay (HPLC) Ph. Eur. (current ed.)

Tetrahydrocannabinol 2.2.29, Monograph < 1.0 % 0.3 %

(THC, total equivalent)

Cannabidiol (CBD, total 7.5 % [6.0 – 9.0] 7.1 %

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, 07 September 2023

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