

Release certificate

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

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: ca. 14% cannabidiol: < 1.0%

Dosage form: flowers

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

Batch: 23C13FP23-F07

Order numbers: containers: 384806 to 384807

> bags: 384809

Grower/drier: Bedrocan Nederland B.V.

P.O. Box 2009

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: irradiation: Soevereinstraat 2 07 June 2023

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

> Venkelbaan 101 07 August 2023 - 09 August 2023

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

> Heembadweg 5 NL-9561 CZ Ter Apel

General analysis

harvest date/period:

13 March 2023

Analysis number: 43147 Report date: 24 April 2023

Microbiology of end product in container

dose:

≥ 10,0 kGy

Analysis number: 45200 Report date: 29 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	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	

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Page 2 Our reference 23C13FP23-F07 Microbial contamination Ph. Eur. (current ed.) Total aerobic microbial 2.6.12, 2.6.13 ≤10² cfu/gram < 10² cfu/gram count (TAMC) Total combined ≤10¹ cfu/gram < 10¹ cfu/gram yeasts/moulds count (TYMC) S. aureus, P. aeruginosa, bile-tolerant gram-Absent (1 gram) conform negative bacteria Aflatoxins Monograph Aflatoxin B₁ ≤ 2 µg/kg $< 2.0 \mu g/kg$ Sum of aflatoxins B₁, B₂, ≤ 4 µg/kg $< 4.0 \mu g/kg$ G1 and G2 Pesticides Ph. Eur. (current ed.) ≤ Limits Ph. Eur. 2.8.13* conform 2.8.13 Heavy metals Ph. Eur. (current ed.) max. 20.0 ppm Lead 2.4.27, 2.2.58 < 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 % 7.2 % 2.2.32 Assay (HPLC) Ph. Eur. (current ed.) Tetrahydrocannabinol 2.2.29, Monograph 14 % [11.2 - 16.8] 15.9 % (THC, total equivalent) Cannabidiol (CBD, total <1.0 % 0.1 % 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 30 June 2024

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

^{*}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.