

Office of Medicinal Cannabis



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

Package size:

5 grams in container, 400 grams in bags

Batch:

24D08FB24E08

Order numbers:

containers: 386346 to 386347

bags:

not applicable

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

08 Apr. 2024

Gamma

NL-9640 CA Veendam Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

08 May 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Fagron Nederland B.V.

date:

15 Aug. 2024 to 19 Aug. 2024

Packager:

Laboratory:

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Heembadweg 5

NL-9561 CZ Ter Apel

General analysis 1.

Analysis number: 48750

Report date: 06 May 2024

Microbiology of end product in container

Analysis number: 50307 Report date: 27 Aug. 2024

Testing method:

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

	Method	Specification	Result
Characters	Monograph	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	Conform
Identification			Conform
Macroscopic botanical characters	Visual	Brown, green granulates of flowers of about 4 to 6 mm in diameter	
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

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

Ph. Eur. (current ed.)			
2.6.12, 2.6.13	≤10² cfu/gram	< 10 ² cf	u/gram
	≤10¹ cfu/gram	< 10 ¹ cf	u/gram
	Absent (1 gram)	Confor	m
Monograph			
	V 25 - 25	< 2.0 μς	-
	≤ 4 µg/kg	< 4.0 μς	g/kg
Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	Conform	m
Ph. Eur. (current ed.)			
2.4.27, 2.2.58	max. 20.0 ppm	< 5 pp	pm
	max. 0.5 ppm	< 0.125 pp	pm
	max. 0.5 ppm	< 0.125 pp	om
Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	6.6 %	
Ph. Eur. (current ed.)			
2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.2 %	
	8.0 % [6.4 – 9.6]	8.4 %	
Ph. Eur. (current ed.)			
2.2.29, Monograph	≤ 1.0 %	< 0.1 %	
BMC-SWV 455	5 gram	± 5.14 gr	ram
		31 Mar. 20	025
	Ph. Eur. (current ed.) 2.8.13 Ph. Eur. (current ed.) 2.4.27, 2.2.58 Ph. Eur. (current ed.) 2.2.32 Ph. Eur. (current ed.) 2.2.29, Monograph Ph. Eur. (current ed.)	2.6.12, 2.6.13 $\leq 10^2 \text{cfu/gram}$ $ \leq 10^1 \text{cfu/gram} $ Absent (1 gram) Monograph $\leq 2 \mu g/kg$ $\leq 4 \mu g/kg$ Ph. Eur. (current ed.) 2.8.13 Ph. Eur. (current ed.) 2.4.27, 2.2.58 max. 20.0 ppm max. 0.5 ppm max. 0.5 ppm max. 0.5 ppm for max. 0.5 ppm max. 0.5 ppm for	2.6.12, 2.6.13 ≤10² cfu/gram <10² cfu ≤10¹ cfu/gram <10¹ cfu Absent (1 gram) Conform Monograph ≤2 μ g/kg <2.0 μ g ≤4 μ g/kg <4.0 μ g Ph. Eur. (current ed.) 2.8.13 Ph. Eur. (current ed.) 2.4.27, 2.2.58 max. 20.0 ppm <5 pp max. 0.5 ppm <0.125 pp max. 0.5 pp max. 0.5 ppm <0.125 pp max. 0.5 p

^{*}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, 30 Aug. 2024

QA, Office of Medicinal Cannabis