

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: 23E01FB23F21 containers: 384878 Order numbers: bags: 384880

Grower/drier: Bedrocan Nederland B.V.

harvest date/period: P.O. Box 2009 01 MAY 2023

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 21 JUN 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

> 17 JUL 2023 to 19 JUL 2023 Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory: 1.

> Heembadweg 5 Analysis number: 44002 NL-9561 CZ Ter Apel

Report date: 19 JUN 2023

General analysis

Microbiology of end product in container

Analysis number: 44911 Report date: 04 AUG 2023

Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

Characters	Method Monograph	Specification 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	Result conform	
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	
572.		other vermin		

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

Our reference 23E01FB23F21					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 ²	cfu/gram
count (TAMC)					•
Total combined		≤10¹ cfu/gra	m	<10 ¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins B_1 , B_2 ,		≤ 4 µg/kg		< 4.0	µg/kg
G_1 and G_2					
Pesticides	Ph. Eur. (current ed.)	≤ Limits Ph. Eur. 2.8.13*		conform	
	2.8.13	2 Lilling Fil. Lui.	2.0.10	COIII	OTTT
Heavy metals	Ph. Eur. (current ed.)				
Lead	2.4.27, 2.2.58	max. 20.0		< 5	ppm
Cadmium		max. 0.5	ppm	<0.125	
Mercury		max. 0.5	ppm	<0.125	
Loss on drying	Ph. Eur. (current ed.)	≤ 10.0	%	8.4	%
	2.2.32				
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	6.3 % [5	5.0 – 7.6]	7.0	%
(THC, total equivalent)					
Cannabidiol (CBD, total		8.0 % [6	5.4 – 9.6]	8.9	%
equivalent)					
Related substances (HPLC)	Ph. Eur. (current ed.)				23
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
equivalent)	D140 0140 / 455	_			
Content of container	BMC-SWV 455	5	gram	± 5.14	
Expiry date				30 JUN	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, 22 August 2023

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