

## 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:

23H07FB23J18

Order numbers:

containers: 385422 and 385423

bags:

385426

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

07 August 2023

NL- 9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

18 October 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

date:

Packager: Fagron Nederland B.V. Venkelbaan 101

27 November 2023 - 01 December 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

1. General analysis

Heembadweg 5

Analysis number: 45475

NL-9561 CZ Ter Apel

Report date: 26 September 2023 Microbiology of end product in container

Analysis number: 47459

Report date: 09 January 2024

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

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Our reference

23H07FB23J18				
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10²	cfu/gram
Total combined		≤10¹ cfu/gram	<10 <sup>1</sup>	cfu/gram
yeasts/moulds count		210 orangram	110	ora/graini
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram-		Absent (1 gram)	confe	orm
negative bacteria		, 5		
Aflatoxins	Monograph			
Aflatoxin B₁		≤ 2 µg/kg	< 2.0	μg/kg
Sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> ,		≤ 4 µg/kg	< 4.0	µg/kg
$G_1$ and $G_2$				
Pesticides	Ph. Eur. (current ed.)	≤ Limits Ph. Eur. 2.8.13*	confe	orm
	2.8.13	2 LIIIII 111. Lui. 2.0.13	COIII	51111
Heavy metals	Ph. Eur. (current ed.)			
Lead	2.4.27, 2.2.58	max. 20.0 ppm		ppm
Cadmium		max. 0.5 ppm	<0.125	
Mercury		max. 0.5 ppm	<0.125	
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	8.7	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.0	%
(THC, total equivalent)				
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.5	%
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	
Expiry date			30 Sept.	2024

<sup>\*</sup>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, 4 June 2024

K. Amponsah / S. Vos – de SchipperQA, Office of Medicinal Cannabis