





## 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

bags:

Package size:

5 grams in container, 400 grams in bags

Batch:

24I16FB24J09

Order numbers:

containers: 386854 386855

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period: 16 Sep. 2024

09 Oct. 2024

P.O. Box 2009

NL-9640 CA Veendam

date:

dose:

Gamma

Synergy Health Ede B.V.

≥ 10,0 kGy

irradiation: Soevereinstraat 2

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V.

Venkelbaan 101

date:

22 Nov. 2024

Laboratory:

NL-2908 KE Capelle a/d IJssel Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis

Analysis number: 50752 Report date: 14 Oct. 2024

Microbiology of end product in container

Analysis number: 51486 Report date: 03 Dec. 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			Conform
Macroscopic botanical	Visual	Brown, green granulates	
characters		of flowers of about 4 to 6	
		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	

Address:

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference

## 24I16FB24J09

Microbial contamination  Total aerobic microbial  count (TAMC)	Ph. Eur. (current ed.) 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			
(TYMC)			
S. aureus, P. aeruginosa,			
bile-tolerant gram-		Absent (1 gram)	Conform
negative bacteria			
Aflatoxins	Monograph		
Aflatoxin B <sub>1</sub>		≤ 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		
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.) 2.2.32	≤ 10.0 %	7.9 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.4 %
(THC, total equivalent)			
Cannabidiol (CBD, total		8.0 % [6.4 – 9.6]	8.7 %
equivalent)			
Related substances (HPLC)	Ph. Eur. (current ed.)		
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
Content of container	BMC-SWV 455	5 gram	± 5.16 gram
Expiry date			31 Aug. 2025

<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, 16 December 2024

K. Amponsah / M. Mennens

QA, Office of Medicinal Cannabis