

## Release certificate

Product:

Cannabis flos, variety Bedrocan (hemp flowers)

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 22%

cannabidiol: < 1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

25C10EY25D02

Order numbers:

containers: 387143 to 387148

bags:

387152

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

10 mar. 2025

dose:

irradiation:

Soevereinstraat 2

02 apr. 2025

≥ 10,0 kGy

Packager:

NL-4879 NN Etten-Leur Fagron Nederland B.V.

date:

11 - 18 apr. 2025

Laboratory:

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

Heembadweg 5

Venkelbaan 101

NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 52739 Report date: 08 apr. 2025

Microbiology of end product in container

Analysis number: 53161 Report date: 29 apr. 2025

Testing method:

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

Method	Specification	Result
Monograph	Odour characteristic for	Conform
	20% of the length of the	
	flower and stalks are	
	The state of the s	
	the flowers	
		Conform
Visual	Brown, green clustered	
	flowers of about 1.5 to	
	3.0 cm length	
Monograph	Gland hairs are mainly observed	Conform
Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	Conform
	Monograph  Visual  Monograph  Ph. Eur. (current ed.)	Monograph  Odour characteristic for Cannabis flower. Leaves shoot out no more than 20% of the length of the flower and stalks are mostly cut off directly under the bottom site of the flowers  Visual  Brown, green clustered flowers of about 1.5 to 3.0 cm length  Monograph  Gland hairs are mainly observed  Ph. Eur. (current ed.)  Comparable with

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## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 25C10EY25D02

25CTUE Y 25DU2			
Foreign material	Visual	Free from insects and other vermin	Conform
Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 <sup>2</sup> cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	< 10 <sup>1</sup> cfu/gram
S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria		Absent (1 gram)	Conform
Aflatoxins	Monograph		
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg	< 2.0 µg/kg
Sum of aflatoxins $B_1$ , $B_2$ , $G_1$ and $G_2$		≤ 4 µg/kg	< 4.0 µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	Conform
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 %	7.6 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 – 26.4]	18.9 %
Cannabidiol (CBD, total equivalent)		<1.0 %	< 0.1 %
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	± 5.14 gram
Expiry date			28 Feb. 2026

<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, 06 may 2025

S. Vos- de Schipper / M. Mennens QA, Office of Medicinal Cannabis