

Release certificate

Product: Cannabis flos, variety Bedrolite (hemp flowers), granulated

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: < 1.0% cannabidiol: ca. 7.5%

Dosage form: flowers

Package size: 5 grams in container, 400 grams in bags

Batch: 24l23FR24J16

Order numbers: containers: 386851 to 386852

bags: 386853

Grower/drier: Bedrocan Nederland B.V.

P.O. Box 2009 23 Sep. 2024

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date:
irradiation: Soevereinstraat 2 16 Oct. 2024

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

Venkelbaan 101 22 – 26 Nov. 2024

NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V.

Heembadweg 5 Analysis number: 50857 NL-9561 CZ Ter Apel Report date: 22 Oct. 2024

1.

Microbiology of end product in container

Analysis number: 51485 Report date: 03 Dec. 2024

General analysis

dose:

≥ 10,0 kGy

harvest date/period:

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	

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

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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/	/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.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*			Conform	
Heavy metals	Ph. Eur. (current ed.)					
Lead	2.4.27, 2.2.58	max. 2	0.0	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	≤ 1	0.0	%	8.0	%
Assay (HPLC)	Ph. Eur. (current ed.)					
Tetrahydrocannabinol	2.2.29, Monograph	<	1.0	%	0.6	%
(THC, total equivalent)						
Cannabidiol (CBD, total equivalent)		7.5 % [6.0 – 9.0]		7.5	%	
Related substances (HPLC)	Ph. Eur. (current ed.)					
Cannabinol (CBN, total	2.2.29, Monograph	<	1.0	%	< 0.1	%
equivalent)	zizizo, monograpii	_		, ,		, ,
Content of container	BMC-SWV 455		5	gram	± 5.14	gram
Expiry date				J	31 Aug.	2025
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^{*}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