Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	Cannabis flos, variety Bedrolite (hemp flowers), granulated						
Country:		to be sold on the pharmaceutical market					
Strength:		rahydrocannabinol: < 1.0% cannabidiol: ca					
Dosage form:	flowers						
Package size:	5 grams in container, 400 grams in bags						
Batch:	24J21FR24K27						
Order numbers:	containers: 386905						
Grower/drier:	bags: 386906	hermonet dete (newight					
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009		harvest date/period:				
	NL- 9640 CA Veendam	21 Oct. 2024					
Gamma	Synergy Health Ede B.V.	date:	dose:				
irradiation:	Soevereinstraat 2	27 Nov. 2024	≥ 10,0 kGy				
maananom	NL-4879 NN Etten-Leur	27 1001 2021	27 NOV. 2024 2 10,0 KGy				
Packager:	Fagron Nederland B.V.	date:					
Ū	Venkelbaan 101	18 Dec. 2024					
	NL-2908 KE Capelle a/d IJss						
Laboratory:	Laboratorium Ofichem B.V.	1. General analysis					
	Heembadweg 5	Analysis number: 51125					
	NL-9561 CZ Ter Apel	Report date: 18 Nov. 202	24				
		2. Microbiology of end product in container					
Analysis number: 51							
		Report date: 10 Jan 2025					
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 bota	<i>nical</i> Visual	Brown, green granulates					
characters		of flowers of about 4 to 6					
		mm in diameter					
Microscopic bota	nical Monograph	Gland hairs are mainly	Conform				
characters		observed					
Thin-layer chromat			Conform				
<b>F</b>	2.2.27, Monograph	reference	0				
Foreign material	Visual	Free from insects and	Conform				
		other vermin					

Address: Hoftoren Rijnstraat 50 The Netherlands

All correspondence addressed to the postal address quoting date and NL-2515 XP THE HAGUE reference of this letter.

Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Page **2** 



	– Our reference 24J21FR24K27					
	Microbial contamination	Ph. Eur. (current ed.)				
	Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 <sup>2</sup>	cfu/gram
Total combined yeasts/moulds count (TYMC)			≤10¹ cfu/gra	im.	< 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
	<i>Sum of aflatoxins B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub></i>		≤ 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	%	7.8	%
	Assay (HPLC)	Ph. Eur. (current ed.)				
	Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	< 1.0	%	0.4	%
	Cannabidiol (CBD, total equivalent)		7.5 % [6	.0 – 9.0]	8.7	%
	Related substances (HPLC)	Ph. Eur. (current ed.)				
	Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
	Content of container Expiry date	BMC-SWV 455	5	gram	± 5.14 30 Sep.	

\*The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl 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, 13 Januari 2025

6 Apparsch

K. Amponsah M. Mennens QA, Office of Medicinal Cannabis