Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	Product: Cannabis flos, variety Bedrolite (hemp flowers), granulated							
Country:		old on the pharmaceuti						
Strength: Dosage form:		drocannabinol: < 1.0%	cannabidiol: ca. 7.5%					
Package size:		flowers 5 grams in container, 400 grams in bags						
Batch:	24I02FR24J02							
Order numbers:	containers: 386768 to 386770							
	bags: Not applicable							
Grower/drier:	Bedroc P.O. Bo	an Nederland B.V. x 2009	harvest date/period: 02 Sep. 2024					
	NL- 964	10 CA Veendam						
Gamma	Synergy Health Ede B.V.		date:		dose:			
irradiation:	Soevereinstraat 2		02 Oct. 20	124	≥ 10,0 kGy			
		9 NN Etten-Leur						
Packager: Fagron Nederland B.			date:					
	Venkelbaan 101 NL-2908 KE Capelle a/d IJssel		24 – 30 Oct. 2024					
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5		1. Gene	eral analysis				
Luboratory.				ysis number: 506	642			
		1 CZ Ter Apel	Report date: 08 Oct. 2024					
		•	 Microbiology of end product in containe Analysis number: 51171 					
			Report date: 06 Nov. 2024					
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021								
		Method	Specification		Result			
Characters		Monograph	Odour characteristic for		Conform			
			annabis flo					
			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			etween 1.5		Conform			
Macroscopic botanical		Visual	rown, aree	en granulates	oomonn			
characters			of flowers of about 4 to 6					
			mm in diameter					
Microscopic botanical		Monograph	Gland hairs are mainly		Conform			
characters Thin-layer chromatography		Ph. Fur (ourrent od)	bserved	rable with	Conform			
		Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with C		Conform			
Foreign material		Visual		insects and	Conform			
			other vermin					

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

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	Our reference 24102FR24J02					
	Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC) Total combined		2.6.12, 2.6.13	≤10² cfu/gram ≤10¹ cfu/gram		< 10 ²	cfu/gram
					< 10 ¹	cfu/gram
	yeasts/moulds count		-			
	(TYMC)					
S. aureus, P. aeruginosa, bile-tolerant gram-						
			Absent (1 gram)		Conform	
	negative bacteria					
	Aflatoxins	Monograph				
	Aflatoxin B1		≤ 2 µg/kg		< 2.0	µg/kg
	Sum of aflatoxins B1, B2,		≤ 4 µg/kg		< 4.0	µg/kg
	G₁ and G₂					
	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	%	6.6	%
	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	0 – 9.0]	8.8	%
	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				31 Aug.	2025

*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, 11 November 2024

Edwarsch

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