Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	duct: Cannabis flos, variety Bedrocan (hemp flowers)							
Country:	to be s	be sold on the pharmaceutical market						
Strength:	tetrahy	drocannabinol: ca. 22%	6	cannabidiol: < 1.0%				
Dosage form:	flowers	flowers						
Package size:	5 gram	5 grams in container, 400 grams in bags						
Batch:	24G08	24G08EY24G31						
Order numbers: containers: 386741 to 386753								
	bags: not applicable							
Grower/drier:		an Nederland B.V.	ha	harvest date/period:				
	P.O. Bo		08 Jul 2024					
		40 CA Veendam						
Gamma		y Health Ede B.V.		ite:	dose:			
irradiation:		einstraat 2	31	Jul 2024	≥ 10,0 kGy			
		9 NN Etten-Leur						
Packager:	Fagron Nederland B.V.			date:				
	Venkelbaan 101			15 – 25 Nov 2024				
		8 KE Capelle a/d IJssel						
Laboratory:		torium Ofichem B.V.	1.	· · · · · · · · · · · · · · · · · · ·				
	Heembadweg 5			Analysis number: 498				
	NL-956	1 CZ Ter Apel	Report date: 06 Aug 2024					
			2. Microbiology of end product in container					
			Analysis number: 51351					
Tastinanathadı	Report date: 20 Nov 2024							
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021								
		Method	Spec	ification	Result			
Characters		Monograph	Odour characteristic for		conform			
				nabis flower. Leaves				
			shoot out no more than					
			20% of the length of the					
			flower and stalks are					
			mos	mostly cut off directly				
			unde	under the bottom site of				
				the flowers				
Identification								
Macroscopic botanical		Visual		vn, green clustered				
characters				ers of about 1.5 to	conform			
				m length				
Microscopic botanical		Monograph		d hairs are mainly	conform			
characters				erved				
Thin-layer chromatography				Comparable with	conform			
		2.2.27, Monograph		reference				

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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 24G08EY24G31					
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/gra	m	< 10 ²	cfu/gram
	Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gra	< 10 ¹	cfu/gram	
	S. aureus, P. aeruginosa,					
	bile-tolerant gram- negative bacteria		Absent (1 gram)		conform	
	Aflatoxins	Monograph				
	Aflatoxin B ₁	0	≤ 2 µg/kg		< 2.0	µg/kg
	Sum of aflatoxins B1, B2, G1 and G2		≤ 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	
	Mercury		max. 0.5	1. A.	< 0.125	
	Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0	%	7.7	%
	Assay (HPLC)	Ph. Eur. (current ed.)				
	Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	22.6	%
	Cannabidiol (CBD, total equivalent)		<1.0	%	0.3	%
	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	± 5.15 30 Jun	_

*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, 28 Nov 2024

THE 6-Bupparsch

K. Amponsah / S. Vos- de Schipper QA, Office of Medicinal Cannabis