Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:			(hemp flowers), granulated			
Country:	to be sold on the pharmaceut tetrahydrocannabinol: ca. 6.3					
Strength: Dosage form:			% cannabidioi : ca. 8%			
Package size:		flowers				
Batch:	5 grams in container, 400 grams in bags 24D01FB24E01					
Order numbers:		ers: 386154				
Order numbers.		386156				
Grower/drier:	bags:	an Nederland B.V.	harvoot data/pariad			
Grower/drief.	P.O. Bo		harvest date/period: 01 April 2024			
		10 CA Veendam	01 April 2024			
Gamma	Synergy Health Ede B.V.		date:	dose:		
irradiation:		einstraat 2	01 May 2024	≥ 10,0 kGy		
maalation		9 NN Etten-Leur		_ 10/0 10/		
Packager:		Nederland B.V.	date:			
5	_	baan 101	04 Jul. 2024 to 08 Jul. 2024			
	NL-290	8 KE Capelle a/d IJssel				
Laboratory:		torium Ofichem B.V.	1. General analysis			
	Heemb	adweg 5	Analysis number: 4862	1		
		1 CZ Ter Apel	Report date: 29 April 20			
			2. Microbiology of end pr			
			Analysis number: 4994			
			Report date: 30 Jul. 202	24		
Testing method:	OMC N	lonograph Cannabis Fl	ower / 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 characters		Visual	Brown, green granulates			
			of flowers of about 4 to 6			
			mm in diameter			
Microscopic botanical		Monograph	Gland hairs are mainly	Conform		
characters Thin-layer chromatography			observed	0		
		Ph. Eur. (current ed.)	Comparable with	Conform		
Frankright material		2.2.27, Monograph	reference	Conforme		
Foreign material		Visual	Free from 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 24D01FB24E01			
Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ² cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10 ¹ cfu/gram	< 10 ¹ ; cfu/gram
<i>S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria</i>		Absent (1 gram)	Conform
Aflatoxins	Monograph		
Aflatoxin B ₁		≤ 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 %	7.5 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.4 %
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.2 %
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 gram 31 Mar. 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, 06 Augustus 2024

The

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