Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

	Product:	Cannal	ois flos, variety Bediol	(hen	np flowers), granulated			
	Country:	to be s	old on the pharmaceut	maceutical market				
	Strength:	tetrahy	drocannabinol: ca. 6.3	%	cannabidiol:	ca. 8%		
	Dosage form:	flowers						
	Package size: 5 grams in container, 400 grams in bags							
	Batch:	22E16FB22K30						
	Order numbers:	contair	containers: 383733 to 383735					
		bags:	not applicable					
			ocan Nederland B.V.					
			x 2009	1	6 May 2022			
	0		40 CA Veendam					
	Gamma		y Health Ede B.V.					
	irradiation:		einstraat 2 '9 NN Etten-Leur		30 November 2022	≥ 10,0 kGy		
	Packager:	Fagron	B.V.	c	late:			
		Venkelbaan 101		C	1 February 2023			
		NL-290	8 KE Capelle a/d IJssel					
	Laboratory:	Labora	torium Ofichem B.V.	1	. General analysis			
		Heembadweg 5			Analysis number: 374	457		
		NL-956	1 CZ Ter Apel		Report date: 28 June	2022		
				2	2. Microbiology of end product in container			
					Analysis number: 419	990		
					Report date: 13 Febru	uary 2023		
	Testing method:	OMC N	1onograph Cannabis Fl	lowe	r / Version 8.0 / Novembe	cannabidiol: ca. 8% /period: r 2022 dose: r 2022 ≥ 10,0 kGy 2023 analysis s number: 37457 date: 28 June 2022 ology of end product in container s number: 41990 date: 13 February 2023 3.0 / November 01, 2021 Result eristic for conform er. Does lks that are cm and e stalks are ad 2.0 cm granulates bout 4 to 6 conform er e mainly conform le with conform		
			Method	Spe	cification	Result		
	Characters		Monograph	Od	our characteristic for	conform		
				Ca	nnabis flower. Does			
				not	contain stalks that are			
				lon	ger than 2.0 cm and			
				on	only 20% of the stalks are			
				bet	 karvest date/period: 16 May 2022 date: 30 November 2022 date: 01 February 2023 1. General analysis Analysis number: 3 Report date: 28 Jur 2. Microbiology of en Analysis number: 4 Report date: 13 Fet ower / Version 8.0 / Novem Specification Odour characteristic for Cannabis flower. Does not contain stalks that are longer than 2.0 cm and 			
	Identification							
	Macroscopic botanical		Visual					
	characters					conform		
	Microscopic botanical characters		Monograph			conform		
				ob				
	Thin-layer chromatography					conform		
			2.2.27, Monograph					
	Foreign material		Visual			conform		
				oth	er vermin			

P.O. Box 16114 NL-2500 BC THE HAGUE The Netherlands Telephone +31 70 340 5113 Telefax +31 70 340 7426 Address: Hoftoren Rijnstraat 50 NL-2515 XP THE HAGUE The Netherlands All correspondence addressed to the postal address quoting date and reference of this letter. Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl Ministry of Health, Welfare and Sport

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Our reference 22E16FB22K30			
Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ² cfu/gram
count (TAMC)			
Total combined		≤10 ¹ 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 B ₁		≤ 2 µg/kg	< 2.0 µg/kg
Sum of aflatoxins B1, B2,		≤ 4 µg/kg	< 4.0 µg/kg
G_1 and G_2			
Pesticides	Ph. Eur. (current ed.)	≤ Limits Ph. Eur. 2.8.13*	conform
	2.8.13		comonn
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.)	≤ 10.0 %	8.1 %
	2.2.32		
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol	2.2.29, Monograph	6.3 % [5.0 – 7.6]	7.0 %
(THC, total equivalent)			
Cannabidiol (CBD, total		8.0 % [6.4 – 9.6]	9.3 %
equivalent)			
Related substances (HPLC)	Ph. Eur. (current ed.)		
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
equivalent)			
Content of container	BMC-SWV 360	5 gram	± 5.15 gram
Expiry date			30 Nov. 2023

*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 Haque, the Netherlands, 15/February 2023

Dr. M.J. van de Velde Headin Office of Medicinal Ganabie de