Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	roduct: Cannabis flos, variety Bedrocan (hemp flowers)						
Country:	to be s	old on the pharmaceut	ical n	narket			
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:	22L12E	22L12EY23C29					
Order numbers:	ers: containers: 384445 to 384454						
	bags:	384456					
Grower/drier:		an Nederland B.V. ox 2009		arvest date/period: 2 Dec. 2022			
	NL- 964	40 CA Veendam					
Gamma	Synerg	y Health Ede B.V.	da	nte:	dose:		
irradiation:	Soever	einstraat 2	29	March 2023	≥ 10,0 kGy		
	NL-487	9 NN Etten-Leur					
Packager:	Fagron B.V.		da	ate:			
	Venkelbaan 101		20	20 April 2023 – 02 May 2023			
	NL-290	8 KE Capelle a/d IJssel					
Laboratory:	Labora	torium Ofichem B.V.	1.	General analysis			
	Heemb	adweg 5		Analysis number: 4135	53		
	NL-956	1 CZ Ter Apel		Report date: 24 Jan. 20	023		
			2.	Microbiology of end p	roduct in container		
				Analysis number: 4364	14		
				Report date: 09 May 20	023		
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021							
		Method	Spec	ification	Result		
Characters		Monograph C		ur characteristic for	conform		
		승규는 것을 잘 한 수 있는		nabis flower. Leaves			
			shoo	ot out no more than			
			20%	of the length of the			
			flow	er and stalks are			
			mos	mostly cut off directly			
			und	under the bottom site of			
			the	lowers			
Identification							
Macroscopic botanical characters		Visual		vn, green clustered	conform		
				ers of about 1.5 to			
			3.0 0	m length			
<i>Microscopic botanical characters</i>		Monograph		nd hairs are mainly	conform		
				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

	22L12EY23C29			
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/gram	< 10² cfu/gram
	Total combined yeasts/moulds count (TYMC)		≤10 ¹ cfu/gram	< 10 ¹ cfu/gram
	S. aureus, P. aeruginosa,			
	bile-tolerant gram- negative bacteria		Absent (1 gram)	conform
	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.) 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	22 % [17.6 – 26.4]	19.2 %
	Cannabidiol (CBD, total equivalent)		<1.0 %	0.1 %
	Related substances (HPLC)	Ph. Eur. (current ed.)		
	Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
	Content of container	BMC-SWV 360	5 gram	± 5.15 gram
	Expiry date			31 Mar. 2024

*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, 19 May 2023

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K. Amponsah / R.V. Goormachtigh QA, Office of Medicinal Cannabis