Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	Cannabis flos, variety Bedrocan (hemp flowers)					
Country:	to be se	to be sold on the pharmaceutical market				
Strength:	tetrahydrocannabinol: ca. 22%			cannabidiol: < 1	1.0%	
Dosage form:	flowers					
Package size:	5 grams in container, 400 grams in bags					
Batch:	22I05EY22K30					
Order numbers:	contain	ers: not available				
	bags:	384746				
Grower/drier:	Bedroc P.O. Bc	an Nederland B.V. ox 2009		rvest date/period: September 2022		
	NL- 964	10 CA Veendam				
Gamma	Synergy Health Ede B.V.		da	te:	dose:	
irradiation:	Soevereinstraat 2		30	November 2022	≥ 10,0 kGy	
	NL-487	9 NN Etten-Leur				
Packager:	Fagron	B.V.	da	te:		
	Venkell	baan 101	24	May 2023		
	NL-290	8 KE Capelle a/d IJssel				
Laboratory:	Labora	torium Ofichem B.V.	1.	General analysis		
	Heemb	adweg 5		Analysis number: 3958	8	
	NL-956	1 CZ Ter Apel		Report date: 13 Octobe	r 2022	
			2.	Microbiology of end pr	oduct in container	
				Analysis number: 4132	7	
				Report date: 06 Januar	y 2023	
Testing method:	OMC N	lonograph Cannabis Fl	ower	/ Version 8.0 / November	01, 2021	
		Method	Snor	ification	Result	
Characters		Monograph		ur characteristic for	conform	
onuractors		Wonogruph		abis flower. Leaves	comonn	
				t out no more than		
				of the length of the		
				er and stalks are		
				tly cut off directly		
				er the bottom site of		
				lowers		
Identification						
Macroscopic bota	nical	Visual	Brov	vn, green clustered	conform	
characters			flow	ers of about 1.5 to		
			3.0 c	m length		
Microscopic botanical		Monograph		d hairs are mainly	conform	
characters				rved		
Thin-layer chromatography		Ph. Eur. (current ed.)	(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 22105EY22K30			
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		≤10 ¹ cfu/gram	< 10 ¹ cfu/gram
(TYMC) S. aureus, P. aeruginosa,			
bile-tolerant gram- negative bacteria		Absent (1 gram)	conform
Aflatoxins	Monograph		
Aflatoxin B1		≤ 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 %	8.4 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 – 26.4]	18.6 %
Cannabidiol (CBD, total equivalent)		<1.0 %	0.2 %
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 360	5 gram	n.a. gram 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 Hague, the Netherlands, 08 June 2023

Choosed

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