Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

	Product:	Cannabis flos, variety Bedrolite (hemp flowers), granulated to be sold on the pharmaceutical market								
	Country: to be sold on the pha Strength: tetrahydrocannabinol									
	Dosage form:	flowers								
	Package size:	5 grams in container, 400 grams in bags								
	Batch:	22126FI								
	Order numbers:	contain	ers: 383676							
		bags: 383677								
	Grower/drier:	Bedrocan Nederland B.V.		har	harvest date/period:					
		P.O. Box 2009			26 September 2022					
	NL-		9640 CA Veendam							
	Gamma	-	y Health Ede B.V.	dat		dose:				
	irradiation:				November 2022	≥ 10,0 kGy				
	-		L-4879 NN Etten-Leur							
	Packager: Fagror				date:					
					23 January – 24 January 2023					
	Laboratory		8 KE Capelle a/d IJssel	1.	General analysis					
	Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel			Analysis number: 3993	7				
					Report date: 08 November 2022 2. Microbiology of end product in container					
NE-950				2						
		Analysis num								
					Report date: 06 Februar					
	Testing method:	OMC N	MC Monograph Cannabis Flower / Version 8.0 / November 01, 2021							
Method S		Specif	ication	Result						
	Characters		Monograph	Odou	r characteristic for	conform				
					abis flower. Does					
					ontain stalks that are					
				-	r than 2.0 cm and					
			•	20% of the stalks are						
	l d a u tifi a ati a u			betwo	een 1.5 and 2.0 cm					
	Identification	ical	Visual	Drow	n groon gronulatoo					
	<i>Macroscopic botanical characters</i>		VISUAI		n, green granulates wers of about 4 to 6	conform				
	characters				n diameter	comonn				
	Microscopic botanical characters		Monograph		hairs are mainly	conform				
			g. april	obsei						
	Thin-layer chromatography		Ph. Eur. (current ed.)	C	omparable with	conform				
			2.2.27, Monograph		reference					
Foreign material			Visual	Free	from insects and	conform				
				other vermin						

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	Our reference 22I26FR22K23						
	Microbial contamination	Ph. Eur. (current ed.)					
	Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10 <sup>2</sup> cfu/gra	m	< 10 <sup>2</sup>	cfu/gram	
	<i>Total combined</i> <i>yeasts/moulds count</i>		≤10¹ cfu/gra	m	< 10 <sup>1</sup>	cfu/gram	
	(TYMC)						
	S. aureus, P. aeruginosa,			,			
	bile-tolerant gram- negative bacteria		Absent (1 gra	m)	conf	orm	
	Aflatoxins	Monograph					
	Aflatoxin B1		≤ 2 µg/kg		< 2.0	µg/kg	
	Sum of aflatoxins B1, B2,		≤ 4 µg/kg		< 4.0	µg/kg	
	G1 and G2						
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	%	8.5	%	
	Assay (HPLC)	Ph. Eur. (current ed.)					
	Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	< 1.0	%	0.3	%	
	Cannabidiol (CBD, total equivalent)		7.5 % [6	.0 – 9.0]	8.0	%	
	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	± 5.14 30 Nov.	0	

\*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, 07 February 2023

Dr. M.J. van de Velde Head, Office of Medicinal Cannabis

Ďr. M.J. van de Velde