Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	Cannabis	s flos, variety Bediol ((hemp flowers), granulated			
Country:	to be sold on the pharmaceutical market					
Strength:	tetrahydı	rocannabinol: ca. 6.39	% cannabidiol: ca. 8%			
Dosage form:	flowers	flowers				
Package size:	5 grams in container, 400 grams in bags					
Batch:	23D03FB23E24					
Order numbers:	containe	rs: 384747				
	bags:	384749				
Grower/drier:		n Nederland B.V.	harvest date/period:			
	P.O. Box	CA Veendam	03 April 2023			
Gamma			date:	dose:		
irradiation:	Soeverei	Health Ede B.V.				
inaulation.		NN Etten-Leur	24 May 2023	≥ 10,0 kGy		
Packager:		lederland B.V.	date:			
ç	Venkelbaan 101		20 June 2023 – 21 June 2023			
	NL-2908	KE Capelle a/d IJssel				
Laboratory:	Laborato	orium Ofichem B.V.	1. General analysis			
	Heembadweg 5		Analysis number: 435	07		
	NL-9561	CZ Ter Apel	Report date: 17 May 2	023		
			2. Microbiology of end product in container			
			Analysis number: 443	84		
			Report date: 04 July 2	023		
Testing method:	OMC Mo	onograph Cannabis Fl	ower / Version 8.0 / November	01, 2021		
	,	Method	Specification	Result		
Characters		Monograph	Odour characteristic for	conform		
		9p.	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						
Macroscopic bota	nical \	Visual	Brown, green granulates			
characters			of flowers of about 4 to 6	conform		
			mm in diameter			
Microscopic botanical		Monograph	Gland hairs are mainly	conform		
characters			observed			
Thin-layer chromatography		Ph. Eur. (current ed.)	Comparable with	conform		
		2.2.27, Monograph	reference	comonn		
Foreign material		Visual	Free from insects and	conform		
. storg. matorial			other vermin	oomonn		

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– Our reference 23D03FB23E24			
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		≤10¹ cfu/gram	< 10 ¹ cfu/gram
yeasts/moulds count (TYMC)			
S. aureus, P. aeruginosa, bile-tolerant gram-		Absent (1 gram)	conform
negative bacteria		Absent (1 grann)	comonn
Aflatoxins	Monograph		
Aflatoxin B ₁	Wonograph	≤ 2 µg/kg	< 2.0 µg/kg
Sum of aflatoxins B_1 , B_2 ,		= 2 μg/kg ≤ 4 μg/kg	< 4.0 μg/kg
G_1 and G_2		= + µg/ng	(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 %	7.3 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.2 %
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.4 %
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	± 5.14 gram
Expiry date			31 May 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, 07 July 2023

post

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