Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	Cannabis flos, variety Bediol (hemp flowers), granulated				
Country:	to be sold on the pharmaceutical market				
Strength:	tetrahydrocannabinol: ca.	6.3% cannabidiol: ca	a. 8%		
Dosage form:	flowers				
Package size:	5 grams in container, 400 grams in bags				
Batch:	23B27FB23E17				
Order numbers:	containers: 384736 to 3	84737			
	bags: 384739				
Grower/drier:	Bedrocan Nederland B.V.	harvest date/period:			
	P.O. Box 2009	27 February 2023			
	NL- 9640 CA Veendam				
Gamma	Synergy Health Ede B.V.	date:	dose:		
irradiation:	Soevereinstraat 2	17 May 2023	≥ 10,0 kGy		
	NL-4879 NN Etten-Leur				
Packager:	Fagron Nederland B.V.	date:			
	Venkelbaan 101	15 June 2023 – 22 June 202	3		
	NL-2908 KE Capelle a/d IJs				
Laboratory:	Laboratorium Ofichem B.V				
	Heembadweg 5	Analysis number: 4284			
	NL-9561 CZ Ter Apel	Report date: 13 April 2			
		2. Microbiology of end p			
		Analysis number: 4438			
		Report date: 04 July 20			
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021					
	Method	Specification	Result		
Characters	Monograph	Odour characteristic for	conform		
		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	<i>nical</i> Visual	Brown, green granulates			
characters		of flowers of about 4 to 6	conform		
		mm in diameter			
Microscopic botar	nical Monograph	Gland hairs are mainly	conform		
characters		observed			
Thin-layer chromat		210 A.	conform		
-	2.2.27, Monograph				
Foreign material	Visual	Free from insects and	conform		
		other vermin			

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All correspondence addressed to the postal address quoting date and NL-2515 XP THE HAGUE 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 23B27FB23E17			
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		≤10¹ cfu/gram	< 101 cfu/gram
(TYMC)			
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 %	7.4 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.1 %
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.5 %
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 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

Sponsel

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