Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	Product: Cannabis flos, variety Bediol (hemp flowers), granulated					
Country:	to be sold on the pharmace	be sold on the pharmaceutical market				
Strength:	tetrahydrocannabinol: ca. 6	6.3% cannabidiol : ca	a. 8%			
Dosage form:	flowers					
Package size:	5 grams in container, 400 g	rams in bags				
Batch:	24B26FB24D03					
Order numbers:	containers: 386344					
	bags: 386345					
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009	harvest date/period: 26 Feb. 2024				
	NL- 9640 CA Veendam					
Gamma	Synergy Health Ede B.V.	date:	dose:			
irradiation:	Soevereinstraat 2 NL-4879 NN Etten-Leur	03 Apr. 2024	≥ 10,0 kGy			
Packager:	Fagron Nederland B.V.	date:				
	Venkelbaan 101	02 Sep. 2024				
	NL-2908 KE Capelle a/d IJs	sel				
Laboratory:	Laboratorium Ofichem B.V	. 1. General analysis				
	Heembadweg 5	Analysis number: 4824	5			
	NL-9561 CZ Ter Apel	Report date: 03 Apr. 20	24			
		2. Microbiology of end pr	oduct in container			
		Analysis number: 5055	3			
		Report date: 17 Sep. 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				
		only 20% of the starks are				
		between 1.5 and 2.0 cm				
Identification			Conform			
Identification <i>Macroscopic bota</i>	<i>anical</i> Visual		Conform			
	anical Visual	between 1.5 and 2.0 cm	Conform			
Macroscopic bota	<i>anical</i> Visual	between 1.5 and 2.0 cm Brown, green granulates				
Macroscopic bota		between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6	Conform Conform			
<i>Macroscopic bota characters Microscopic bota characters</i>	<i>nical</i> Monograph	between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6 mm in diameter Gland hairs are mainly observed	Conform			
<i>Macroscopic bota characters Microscopic bota</i>	<i>nical</i> Monograph tography Ph. Eur. (current ed	between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6 mm in diameter Gland hairs are mainly observed d.) Comparable with				
<i>Macroscopic bota characters Microscopic bota characters Thin-layer chroma</i>	nical Monograph tography Ph. Eur. (current ec 2.2.27, Monograph	between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6 mm in diameter Gland hairs are mainly observed d.) Comparable with reference	Conform Conform			
<i>Macroscopic bota characters Microscopic bota characters</i>	<i>nical</i> Monograph tography Ph. Eur. (current ed	between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6 mm in diameter Gland hairs are mainly observed d.) Comparable with	Conform			

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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 24B26FB24D03				
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	< 10 ¹	cfu/gram
(TYMC)				
S. aureus, P. aeruginosa,			0.1	
bile-tolerant gram- negative bacteria		Absent (1 gram)	Confo	orm
Aflatoxins	Monograph			
Aflatoxin B ₁		≤ 2 µg/kg	< 2.0	
<i>Sum of aflatoxins B₁, B₂,</i> <i>G</i> 1 and <i>G</i> 2		≤ 4 µg/kg	< 4.0	µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	Confe	orm
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 %	7.2	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	5.6	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	7.6	%
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 455	5 gram	± 5.15 31 Jan.	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, 20 September 2024

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K. Amponsah / M. Mennens QA, Office of Medicinal Cannabis