Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:	Cannabis flos, variety Bedrolite (hemp flowers), granulated					
Country:	to be sold on the pharmaceu	to be sold on the pharmaceutical market				
Strength:	tetrahydrocannabinol: < 1.0%	6 cannabidiol: ca.	cannabidiol: ca. 7.5%			
Dosage form:	flowers					
Package size:	5 grams in container, 400 gra	ams in bags				
Batch:	24F10FR24G03					
Order numbers:	containers: 386404					
	bags: 386405					
Grower/drier:	Bedrocan Nederland B.V.	harvest date/period:				
	P.O. Box 2009	10 Jun. 2024				
	NL- 9640 CA Veendam					
Gamma	Synergy Health Ede B.V.	date:	dose:			
irradiation:	Soevereinstraat 2	03 Jul. 2024 ≥ 10,0 kGy				
D	NL-4879 NN Etten-Leur					
Packager:	Fagron Nederland B.V.	date:				
	Venkelbaan 101	06 Aug. 2024 to 09 Aug. 2024				
Labaratanu	NL-2908 KE Capelle a/d IJsse Laboratorium Ofichem B.V.					
Laboratory:	Heembadweg 5	1. General analysis	E			
	NL-9561 CZ Ter Apel	Analysis number: 4953				
	NE-9501 CZ TELAPEL	Report date: 09 Jul. 2024				
		2. Microbiology of end product in container				
	Analysis number: 50259 Report date: 22 Aug. 2024 : OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021					
Testing method:						
	eme menegraph earmable i		01,2021			
	Method	Specification	Result			
Characters	Monograph	Odour characteristic for	Conform			
		Cannabis flower. Does				
		not contain stalks that are				
		not contain stalks that are longer than 2.0 cm and				
		longer than 2.0 cm and only 20% of the stalks are				
		longer than 2.0 cm and				
Identification		longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm	Conform			
Macroscopic bota	<i>nical</i> Visual	longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm Brown, green granulates	Conform			
	<i>nical</i> Visual	longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6	Conform			
<i>Macroscopic bota characters</i>		longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6 mm in diameter				
<i>Macroscopic bota characters Microscopic bota</i>		longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm Brown, green granulates of flowers of about 4 to 6 mm in diameter Gland hairs are mainly	Conform Conform			
<i>Macroscopic bota characters Microscopic bota characters</i>	<i>nical</i> Monograph	longer than 2.0 cm and only 20% of the stalks are 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.)	longer than 2.0 cm and only 20% of the stalks are 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 Comparable with				
<i>Macroscopic bota characters Microscopic bota characters Thin-layer chromat</i>	nical Monograph tography Ph. Eur. (current ed.) 2.2.27, Monograph	longer than 2.0 cm and only 20% of the stalks are 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 Comparable with reference	Conform Conform			
<i>Macroscopic bota characters Microscopic bota characters</i>	<i>nical</i> Monograph tography Ph. Eur. (current ed.)	longer than 2.0 cm and only 20% of the stalks are 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 Comparable with	Conform			

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Office of Medicinal Cannabis

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	2					
	Our reference					
	24F10FR24G03					
	Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial		2.6.12, 2.6.13	≤10² cfu/gram		< 10 ²	cfu/gram
	count (TAMC)		91 million - 147 - 75			
	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					
	Aflatoxins	Monograph				
	Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg
	Sum of aflatoxins B_{1} , B_{2} ,		≤ 4 µg/kg		< 4.0	µg/kg
	G_1 and G_2					
	Pesticides	Ph. Eur. (current ed.)	≤ Limits Ph. Eur. 2.8.13*		Conf	orm
		2.8.13		2.0.15	Com	UIII
	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.)	≤ 10.0	%	8.1	%
		2.2.32				
	Assay (HPLC)	Ph. Eur. (current ed.)				
	Tetrahydrocannabinol	2.2.29, Monograph	< 1.0	%	0.4	%
	(THC, total equivalent)					
	Cannabidiol (CBD, total		7.5 % [6	.0 – 9.0]	8.8	%
	equivalent)					
	Related substances (HPLC)	Ph. Eur. (current ed.)				
	Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
	equivalent)					
	Content of container	BMC-SWV 455	5	gram	± 5.14	gram
	Expiry date				31 May	2025

*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, 27 Aug. 2024

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