Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

	Cannabis flos, variety Bediol (hemp flowers), granulated					
5	to be sold on the pharmaceutical market tetrahydrocannabinol: ca. 6.3% cannabidiol : ca. 8%					
-	tetrahydrocannabinol: ca. 6.3 flowers	d. 0%				
-	5 grams in container, 400 gra	ms in hags				
0	24C18FB24D17	ino in bago				
Order numbers: containers: 386159, 386160, 386216						
	bags: not applicable					
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009	harvest date/period: 18 Mar. 2024				
1	NL- 9640 CA Veendam					
Gamma	Synergy Health Ede B.V.	date:	dose:			
irradiation:	Soevereinstraat 2	17 Apr. 2024	≥ 10,0 kGy			
	NL-4879 NN Etten-Leur					
Packager:	Fagron Nederland B.V.	date:				
	Venkelbaan 101	31 Jul. 2024				
	NL-2908 KE Capelle a/d IJsse					
· · · · · · · · · · · · · · · · · · ·	Laboratorium Ofichem B.V.	1. General analysis	_			
	Heembadweg 5		Analysis number: 48456			
	NL-9561 CZ Ter Apel					
	2. Microbiology of end product in conta Analysis number: 50306					
Testing method:	Report date: 27 Aug. 2024 thod: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021					
	Method	Specification	Result			
Characters	Monograph	Odour characteristic for	Conform			
		Cannabis flower. Does				
	not contai					
		longer than 2.0 cm and				
		only 20% of the stalks are				
		between 1.5 and 2.0 cm				
Identification		_	Conform			
Macroscopic botani	<i>ical</i> Visual	Brown, green granulates				
characters		of flowers of about 4 to 6				
Mi	Newswerk	mm in diameter	Conforme			
Microscopic botanic	cal Monograph	Gland hairs are mainly observed	Conform			
characters Thin-layer chromatog	graphy Ph. Eur. (current ed.)		Conform			
min-layer chromatog	2.2.27, Monograph	Comparable with reference	Comorni			
Foreign material	Visual	Free from insects and	Conform			
. stolgn matorial	1000	other vermin	Comon			

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Page

2				
Our reference 24C18FB24D17				
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ²	cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	< 10 ¹	cfu/gram
			Cant	
<i>S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria</i>		Absent (1 gram)	Conf	orm
Aflatoxins	Monograph			
Aflatoxin B ₁		≤ 2 µg/kg	< 2.0	µg/kg
Sum of aflatoxins B1, B2,		≤ 4 µg/kg		µg/kg
G1 and G2				
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	Conf	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 %	7.7	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.7	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 - 9.6]	9.0	%
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 455	5 gram	± 5.14 28 Feb.	-

*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, 30 Aug. 2024



S. Vos- de Schipper / M. Mennens QA, Office of Medicinal Cannabis