Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	Cannabis flos, variety Bed				
Country:	to be sold on the pharmac				
Strength:	tetrahydrocannabinol: ca. :	22% cannabidiol: <	1.0%		
Dosage form:	flowers	averagin here			
	Package size: 5 grams in container, 400 grams in bags Batch: 23H28EY23K08				
Batch:					
Order numbers:					
Grower/drier:	bags: not applicable Bedrocan Nederland B.V.				
Grower/drier.	P.O. Box 2009				
	NL- 9640 CA Veendam	28 August 2023			
Gamma	Synergy Health Ede B.V.	date:	dose:		
irradiation:	Soevereinstraat 2	08 November 2023	≥ 10,0 kGy		
maanatom	NL-4879 NN Etten-Leur		,.		
Packager:	Fagron Nederland B.V.	date:			
	Venkelbaan 101	10 April 2024			
	NL-2908 KE Capelle a/d IJs				
Laboratory:	Laboratorium Ofichem B.V				
(1), Teddaff, D. art (add, past: stand) ( Triangle)	Heembadweg 5	Analysis number: 4584	17		
	NL-9561 CZ Ter Apel	Report date: 16 Octobe			
		2. Microbiology of end p	roduct in container		
		Analysis number: 4881	12		
		Report date: 30 April 2	024		
Testing method:					
	Method	Specification	Result		
Characters	Monograph	Odour characteristic for	conform		
		Cannabis flower. Leaves			
		shoot out no more than			
		20% of the length of the			
		flower and stalks are			
		mostly cut off directly			
		under the bottom site of			
		the flowers			
Identification					
Macroscopic botar	<i>nical</i> Visual	Brown, green clustered			
characters		flowers of about 1.5 to	conform		
14:	ing Name	3.0 cm length			
Microscopic botan	<i>ical</i> Monograph	Gland hairs are mainly observed	conform		
characters	aranhu Dh Eur laureata		aanfarm		
ппп-тауег спготатс	<i>ography</i> Ph. Eur. (current e	_	conform		
	2.2.27, Monograph	reierence			

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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

23H28EY23K08					
Foreign material	Visual	Free from insects and other vermin	conf	conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 <sup>2</sup>	cfu/gram	
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	< 10 <sup>1</sup>	cfu/gram	
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gram)	conf	orm	
Aflatoxins	Monograph				
Aflatoxin B <sub>1</sub>		≤ 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*	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  %	8.2	%	
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 – 26.4	] 17.7	%	
Cannabidiol (CBD, total equivalent)		<1.0 %	0.1	%	
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0   %	< 0.1	%	
Content of container	BMC-SWV 455	5 gram	± 5.15	gram	
Expiry date			30 Sep	2024	
<i>equivalent)</i> Content of container			± 5.15	grar	

\*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, 18 June 2024

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