Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product: Country:		<b>bis flos, variety Bedroc</b> old on the pharmaceut							
Strength:		drocannabinol: ca. 22%							
Dosage form:		flowers							
Package size:	5 grams in container, 400 grams in bags								
Batch:	24K11EY24L04								
Order numbers:	containers: 386928 to 386934								
	bags: 386935								
Grower/drier:		an Nederland B.V. ox 2009	harvest date/period: 11 Nov 2024						
	NL- 964	40 CA Veendam							
Gamma	Synerg	y Health Ede B.V.	date: dose:						
irradiation:		einstraat 2 9 NN Etten-Leur	04 Dec 2024 ≥ 10,0 kGy						
Packager:	Fagron Nederland B.V.		date:						
	Venkelbaan 101		21 – 29 Jan 2025						
	NL-290	8 KE Capelle a/d IJssel							
Laboratory:	Laboratorium Ofichem B.V.		1. General analysis						
	Heembadweg 5		Analysis number: 51408						
	NL-956	1 CZ Ter Apel	Report date: 10 Dec 2024						
	2. Microbiology of end product in								
	Analysis number: 52249								
			Report date: 05 Feb 2025						
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021									
		Method	Specification Result						
Characters	Monograph		Odour characteristic for conform	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		×							
<i>Macroscopic botanical characters</i>		Visual	Brown, green clustered						
			flowers of about 1.5 to conform						
Adi		Managenet	3.0 cm length						
Microscopic botanical		Monograph	Gland hairs are mainly conform observed						
characters Thin-layer chromatography		Ph. Fur (ourrant ad)							
		Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with conform reference						

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Our reference 24K11EY24L04					
Foreign material	Visual	Free from insects and other vermin		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		≤10 <sup>1</sup> cfu/gram		< 10 <sup>1</sup>	cfu/gram
(TYMC) S. aureus, P. aeruginosa,			*		
bile-tolerant gram- negative bacteria		Absent (1 gram)		conform	
Aflatoxins	Monograph				
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins $B_1, B_2, G_1$ and $G_2$		≤ 4 µg/kg		< 4.0	µg/kg
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	%	7.1	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	19.9	%
Cannabidiol (CBD, total equivalent)		<1.0	%	0.2	%
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 31 Oct	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, 07 February 2025

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