Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:		ois flos, variety Bedroc						
Country:		to be sold on the pharmaceutical market						
Strength:	100	tetrahydrocannabinol: ca. 22% cannabidiol: < 1.0%						
Dosage form:	flowers							
Package size:	5 grams in container, 400 grams in bags							
Batch:		24F17EY24G10						
Order numbers:		ontainers: 386615 to 386627						
Cuercuen/duien	bags:	not applicable	haw wat data /aania					
Grower/drier:		an Nederland B.V. ox 2009	harvest date/period: 17 June 2024					
	NL- 96	40 CA Veendam						
Gamma	Synerg	y Health Ede B.V.	date:	dose:				
irradiation:	Soever	reinstraat 2	10 July 2024	≥ 10,0 kGy				
	NL-4879 NN Etten-Leur							
Packager:	Fagron	Nederland B.V.	date:					
	Venkelbaan 101		16 Oct. 2024 – 24 Oct. 2024					
		NL-2908 KE Capelle a/d IJssel						
Laboratory:	Laboratorium Ofichem B.V.		1. General analy					
		adweg 5	Analysis number: 49647					
NL-956		1 CZ Ter Apel	Report date: 15 July 2024					
			2. Microbiology of end product in container					
			Analysis num					
Taatio o waatha da		Annanuanh Canaahia El	Report date: 28 October 2024					
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021								
		Method	Specification	Result				
Characters		Monograph	Odour characteristic	for conform				
			Cannabis flower. Leaves					
			shoot out no more t					
			20% of the length of the					
			flower and stalks are					
			mostly cut off directly					
			under the bottom site of					
			the flowers					
Identification		Marial	D					
Macroscopic botanical		Visual	Brown, green cluste					
characters			flowers of about 1.5 3.0 cm length	to comorni				
Microcopic botanical		Monograph	Gland hairs are main	nly conform				
<i>Microscopic botanical characters</i>		Monograph	observed	uny comorni				
Thin-layer chromatography		Ph. Eur. (current ed.)	Comparable wit	h conform				
	- 3. 3,5)	2.2.27, Monograph	reference					
		,						

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Our reference

24F17EY24G10					
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/gran	n	< 10²	cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10 ¹ cfu/gran	n	< 10 ¹	cfu/gram
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gram)		conform	
Aflatoxins	Monograph				
Aflatoxin B1		≤ 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*		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	%	9.1	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	- 26.4]	21.7	%
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				31 May	

*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 Oct 2024

6. Anpensch

K. Amponsah / S. Vos- de Schipper QA, Office of Medicinal Cannabis