Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	Product: Cannabis flos, variety Bedrobinol (hemp flowers)							
Country:		old on the pharmaceuti						
Strength:		drocannabinol: ca. 13.5	%	cannabidiol : < 1.0%				
Dosage form:	flowers							
Package size: Batch:	5 grams in container, 400 grams in bags <b>24F03FA24G03</b>							
Order numbers:	24F03FA24G03 containers: 386455 and 386643							
order numbers.	bags: not applicable							
Grower/drier:	0	an Nederland B.V.	harvest	date/period:				
drowen/driet.		P.O. Box 2009		03 Jun. 2024				
	NL- 9640 CA Veendam							
Gamma	Synerg	y Health Ede B.V.	date:		dose:			
irradiation:	Soever	Soevereinstraat 2		2024	≥ 10,0 kGy			
	NL-4879 NN Etten-Leur							
Packager:	Fagron Nederland B.V.		date:					
	Venkelbaan 101		09 to 10 Sep. 2024					
	NL-2908 KE Capelle a/d IJssel							
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5		1. Ge	eneral analysis				
			An	alysis number: 495	34			
	NL-956	1 CZ Ter Apel		Report date: 09 Jul. 2024				
					nd product in container			
			Analysis number: 505					
	Report date: 17 Sep. 2024 OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021							
Testing method:	OMCIN	lonograph Cannabis Fl	wer / Ver	sion 8.0 / Novembei	r 01, 2021			
		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					
			nostly cut off directly					
			under the bottom site of the flowers					
Identification			the nowe	15	Conform			
Macroscopic botanical		Visual	Brown a	reen clustered	Comonn			
characters		Visual		f about 1.5 to				
			3.0 cm length					
Microscopic botanical characters		Monograph	Gland hairs are mainly observed		Conform			
		anne - states - Orace IV a						
Thin-layer chromatography		Ph. Eur. (current ed.)		Comparable with Conform reference				
		2.2.27, Monograph						

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0					
2					
Our reference 24F03FA24G03					
	Viewel	Erec from incost	a and	Conf	o * 170
Foreign material	Visual	Free from insects and		Conform	
		other vermi	n		
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 <sup>2</sup>	cfu/gram
Total combined		≤10¹ cfu/gram		< 10 <sup>1</sup>	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		Conform	
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin $B_1$	monograph	≤ 2 µg/kg		< 20	µg/kg
Sum of aflatoxins $B_1$ , $B_2$ ,		≤ 4 μg/kg			µg/kg
$G_1$ and $G_2$		= + µg/ng		< <del>1</del> .0	P9/N9
Pesticides	Ph. Eur. (current ed.)				
	2.8.13	≤ Limits Ph. Eur. 2.8.13* C		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	%	8.4	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	13.5 % [10.8	3 – 16.2]	13.4	%
(THC, total equivalent)					
Cannabidiol (CBD, total		<1.0	%	< 0.1	%
equivalent)					, -
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
equivalent)	2.2.20, wonograph	1.0	/0	< 0.1	70
Content of container	BMC-SWV 455	F	gram	± 5.15	aram
	DIVIC-3VV 433	5	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, 20 September 2024

K. Amponsah / M. Mehnens

K. Amponsah / M. Mehnens QA, Office of Medicinal Cannabis