Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	Cannabis flos, variety Bedica (hemp flowers), granulated							
Country:	to be s	b be sold on the pharmaceutical market						
Strength:	tetrahydrocannabinol: ca. 14%			cannabidiol : < 1.0%				
Dosage form:	flowers							
Package size:	5 grams in container, 400 grams in bags							
Batch:	24D15FP24E22							
Order numbers:	containers: 386163							
	bags:	386165						
Grower/drier:		an Nederland B.V. ox 2009		rvest date/period: April 2024				
	NL- 9640 CA Veendam							
Gamma	Synergy Health Ede B.V.		da	te:	dose:			
irradiation:		einstraat 2 9 NN Etten-Leur	22	22 May 2024 ≥ 10,0 kGy				
Packager:	Fagron Nederland B.V.		da	date:				
Ū	Venkelbaan 101		11	11 to 13 June 2024				
	NL-2908 KE Capelle a/d IJssel							
Laboratory:	Labora	torium Ofichem B.V.	1.	General analysis				
	Heembadweg 5 NL-9561 CZ Ter Apel			Analysis number: 48814 Report date: 14 May 2024 2. Microbiology of end product in container				
			2.					
				Analysis number: 4968	30			
				Report date: 03 July 20	)24			
Testing method:	OMC N	1onograph Cannabis Fl	ower	/ Version 8.0 / November	01, 2021			
		Method	Snec	ification	Result			
Characters		Monograph		ur characteristic for	Conform			
				abis flower. Does				
				ontain stalks that are				
				er than 2.0 cm and				
				20% of the stalks are				
				een 1.5 and 2.0 cm				
Identification					Conform			
Macroscopic botanical		Visual	Brow	/n, green granulates				
characters				owers of about 4 to 6				
				in diameter				
<i>Microscopic botanical characters</i>		Monograph	Gland hairs are mainly observed		Conform			
Thin-layer chromatography		Ph. Eur. (current ed.)		Comparable with Conform				
		2.2.27, Monograph	,	reference	Comonn			
Foreign material		Visual	Free	from insects and	Conform			
i oreign material		visual		r vermin	Comonn			
			other	vernin				

P.O. Box 16114 NL-2500 BC THE HAGUE The Netherlands Telephone +31 70 340 5113 Telefax +31 70 340 7426

Address: Hoftoren Rijnstraat 50 The Netherlands

All correspondence addressed to the postal address quoting date and NL-2515 XP THE HAGUE reference of this letter.

Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl Ministry of Health, Welfare and Sport

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raye				
2				
Our reference 24D15FP24E22				
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
<i>Total combined</i> <i>yeasts/moulds count</i>		≤10¹ cfu/gram	< 10 <sup>1</sup>	cfu/gram
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram-		Absent (1 gram)	Conf	orm
negative bacteria				
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*	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   %	6.4	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2 – 16.8]	13.8	%
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	BMC-SWV 455	5 gram	± 5.15	gram
Expiry date			31 March	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, 08 July 2024

Amonseh

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