Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	, , , , , , , , , , , , , , , , , , , ,						
Country:	to be sold on the pharmaceutical market						
Strength:	tetrahydrocannabinol: < 1.0	Cannabidioi: ca. 7.	cannabidiol: ca. 7.5%				
Dosage form:		flowers					
Package size: Batch:	5 grams in container, 400 grams in bags <b>22L12FR23C08</b>						
Order numbers:	containers: 384267						
order numbers.	bags: 384269						
Grower/drier:	Bedrocan Nederland B.V.	harvest date/period:					
diowen/dilei.	P.O. Box 2009	12 December 2022					
	NL- 9640 CA Veendam						
Gamma	Synergy Health Ede B.V.	date:	dose:				
irradiation:	Soevereinstraat 2	08 March 2023	≥ 10,0 kGy				
	NL-4879 NN Etten-Leur						
Packager:	Fagron B.V.	date:					
	Venkelbaan 101	03 April 2023 – 04 April 2023	03 April 2023 – 04 April 2023				
	NL-2908 KE Capelle a/d IJs	sel					
Laboratory:	Laboratorium Ofichem B.V	1. General analysis					
	Heembadweg 5	Analysis number: 41352					
	NL-9561 CZ Ter Apel	Report date: 24 January					
		2. Microbiology of end pro	duct in container				
		Analysis number: 43357					
		Report date: 20 April 202					
Testing method:	OMC Monograph Cannabis	Flower / Version 8.0 / November 0	1, 2021				
	Method	Specification	Result				
Characters	Monograph	Odour characteristic for	conform				
		Cannabis flower. Does					
		not contain stalks that are					
		longer than 2.0 cm and					
		only 20% of the stalks are					
		between 1.5 and 2.0 cm					
Identification							
Macroscopic bota	<i>anical</i> Visual	Brown, green granulates					
characters		of flowers of about 4 to 6	conform				
		mm in diameter					
Microscopic bota	nical Monograph	Gland hairs are mainly	conform				
characters	to graphy Dh. Fur lourrant of	observed	aanfarm				
Thin-layer chromat	tography Ph. Eur. (current ec 2.2.27, Monograph		conform				
Foreign material	Z.Z.27, Monograph Visual	Free from insects and	conform				
i oreigii material	visual	other vermin	Comorni				
		Galer Vermin					

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Ph. Eur. (current ed.)				
2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 <sup>2</sup>	cfu/gram
	≤10¹ cfu/gra	m	< 10 <sup>1</sup>	cfu/gram
	Absent (1 gra	im)	conf	orm
Monograph				
	≤ 2 µg/kg		< 2.0	µg/kg
	≤ 4 µg/kg		< 4.0	µg/kg
Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. :	2.8.13*	conf	orm
Ph. Eur. (current ed.)				
2.4.27, 2.2.58	max. 20.0	ppm	< 5	ppm
	max. 0.5	ppm	< 0.125	ppm
	max. 0.5	ppm	< 0.125	ppm
Ph. Eur. (current ed.) 2.2.32	≤ 10.0	%	8.4	%
Ph. Eur. (current ed.)				
2.2.29, Monograph	< 1.0	%	0.3	%
	7.5 % [6	.0 – 9.0]	8.2	%
Ph. Eur. (current ed.)				
2.2.29, Monograph	≤ 1.0	%	< 0.1	%
BMC-SWV 360	5	gram	± 5.15 31 March	<b>O</b>
	2.6.12, 2.6.13 Monograph Ph. Eur. (current ed.) 2.8.13 Ph. Eur. (current ed.) 2.4.27, 2.2.58 Ph. Eur. (current ed.) 2.2.32 Ph. Eur. (current ed.) 2.2.29, Monograph Ph. Eur. (current ed.) 2.2.29, Monograph	2.6.12, 2.6.13 $\leq 10^2 \text{ cfu/gras}$ $\leq 10^1 \text{ cfu/gras}$ $\leq 10^1 \text{ cfu/gras}$ Monograph $\leq 2 \mu g/kg$ Ph. Eur. (current ed.) $\leq 4 \mu g/kg$ 2.8.13 $\leq \text{Limits Ph. Eur. 32}$ Ph. Eur. (current ed.) $\leq \text{Limits Ph. Eur. 32}$ 2.4.27, 2.2.58max. 20.0max. 0.5max. 0.5Ph. Eur. (current ed.) $\leq 10.0$ 2.2.32 $\leq 10.0$ Ph. Eur. (current ed.) $< 1.0$ 2.2.29, Monograph $< 1.0$ 2.2.29, Monograph $\leq 1.0$	2.6.12, 2.6.13 $\leq 10^2 \text{ cfu/gram}$ $\leq 10^1 \text{ cfu/gram}$ $\leq 10^1 \text{ cfu/gram}$ Monograph $\leq 2 \mu g/kg$ Ph. Eur. (current ed.)2.8.13Ph. Eur. (current ed.)2.4.27, 2.2.58max. 20.0 ppmPh. Eur. (current ed.)2.2.32Ph. Eur. (current ed.)2.2.32Ph. Eur. (current ed.)2.2.29, Monograph $< 1.0 \%$ Ph. Eur. (current ed.)2.2.29, Monograph $< 1.0 \%$ $< 1.0 \%$	2.6.12, 2.6.13 $\leq 10^2 \text{ cfu/gram}$ $< 10^2 \text{ cfu/gram}$ $\leq 10^1 \text{ cfu/gram}$ $< 10^1 \text{ cm}^2$ $\leq 10^1 \text{ cfu/gram}$ $< 10^1 \text{ cm}^2$ Monograph $\leq 2 \mu g/kg$ $< 2.0$ $\leq 4 \mu g/kg$ $< 4.0$ Ph. Eur. (current ed.) $\leq 1 \text{ imits Ph. Eur. 2.8.13*}$ conf2.8.13 $= 1 \text{ imits Ph. Eur. 2.8.13*}$ confPh. Eur. (current ed.) $\leq 1.0.0 \text{ ppm}$ $< 5 \text{ max. 0.5 ppm}$ 2.4.27, 2.2.58 $\max 20.0 \text{ ppm}$ $< 5 \text{ max. 0.5 ppm}$ Ph. Eur. (current ed.) $\leq 10.0 \%$ $8.4 \text{ cm}^2$ 2.2.32Ph. Eur. (current ed.) $\leq 1.0 \%$ $0.3 \text{ cm}^2$ Ph. Eur. (current ed.) $\leq 1.0 \%$ $< 0.1 \text{ cm}^2$ 2.2.29, Monograph $\leq 1.0 \%$ $< 0.1 \text{ cm}^2$ BMC-SWV 360 $5 \text{ gram}$ $\pm 5.15 \text{ cm}^2$

\*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, 25 April 2023

Dr. M.J. van de Velde Head, Office of Medicinal Cannabi Dr. M.J. van de Velde