Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	Cannabis flos, variety Bed	rocan (hemp flowers)					
Country:	to be sold on the pharmaceutical market						
Strength:	tetrahydrocannabinol: ca.	22% cannabidiol: <	< 1.0%				
Dosage form:	flowers						
Package size:	5 grams in container, 400 grams in bags						
Batch:	22H29EY22K23						
Order numbers:	containers: 383663 to	383674 and 383679					
	bags: not applicable						
Grower/drier:	Bedrocan Nederland B.V.	harvest date/period:	harvest date/period:				
	P.O. Box 2009	29 August 2022	29 August 2022				
	NL- 9640 CA Veendam						
Gamma	Synergy Health Ede B.V.	date:	dose:				
irradiation:	Soevereinstraat 2	23 November 2022 ≥ 10,0 k0					
	NL-4879 NN Etten-Leur						
Packager:	Fagron B.V.	date:	date:				
	Venkelbaan 101	06 January 2023 – 25 Janu	06 January 2023 – 25 January 2023				
	NL-2908 KE Capelle a/d IJssel						
Laboratory:	Laboratorium Ofichem B.V	<ol> <li>General analysis</li> </ol>					
	Heembadweg 5	Analysis number: 394	Analysis number: 39463				
	NL-9561 CZ Ter Apel	Report date: 14 Octob	Report date: 14 October 2022				
		2. Microbiology of end	2. Microbiology of end product in container				
		Analysis number: 416	656				
		Report date: 26 Janua	ary 2023				
Testing method:	OMC Monograph Cannabi	s Flower / Version 8.0 / Novembe	er 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					
		mostly cut off directly					
		under the bottom site of					
		the flowers					
Identification							
Macroscopic bota	<i>nical</i> Visual	Brown, green clustered					
characters		flowers of about 1.5 to	conform				
		3.0 cm length					
Microscopic bota	<i>nical</i> Monograph	Gland hairs are mainly	conform				
characters		observed	-				
characters Thin-layer chromat		d.) Comparable with	conform				
	<i>ography</i> Ph. Eur. (current e 2.2.27, Monograph	d.) Comparable with	conform				

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Our reference					
22H29EY22K23					
Foreign material	Visual	Free from insects and		conform	
		other vermi	n		
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gra	m	<10 <sup>2</sup>	cfu/gram
count (TAMC)					
Total combined		≤10 <sup>1</sup> 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 B1		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins $B_{1}$ , $B_{2}$ ,		≤ 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.)	≤ 10.0	%	9.1	%
	2.2.32				
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	22 % [17.6	6 – 26.4]	20.3	%
(THC, total equivalent)					
Cannabidiol (CBD, total		<1.0	%	0.2	%
equivalent)					
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
equivalent)					
Content of container	BMC-SWV 360	- 5	gram 🕤	± 5.15	gram
Expiry date				Nov.	2023

\*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 2023

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