Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product:		flos, variety Bedroca						
Country: Strength:	to be sold on the pharmaceutical market tetrahydrocannabinol: ca. 22% cannabidiol: < 1.0%							
Dosage form:	flowers							
Package size:	-	n container, 400 gran	ns in ba	igs				
Batch:	22I05EY22K30							
Order numbers:	containers: 383724 to 383730							
	bags: 383732							
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009			harvest date/period:				
	NL- 9640 CA Veendam			05 September 2022				
Gamma			date	date: dose:				
		gy Health Ede B.V. reinstraat 2		ovember 2022	≥ 10,0 kGy			
	NN Etten-Leur	n-Leur		≥ 10,0 kGy				
Packager:	Fagron B.	B.V.		date:				
	Venkelbaan 101			19 December 2022 – 22 December 2022				
	NL-2908 KE Capelle a/d IJssel Laboratorium Ofichem B.V. 1. General analysis							
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5			General analysis				
				Analysis number: 39588				
	NL-9561 C	CZ Ter Apel		Report date: 18 October 2022				
	2. Microbiology of end product in container							
				Analysis number: 413				
		Report date: 06 January 2023						
lesting method:	Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021							
	N	lethod	Specific	ation	Result			
Characters	5		Odour characteristic for Cannabis flower. Leaves		conform			
			Cannal	ois flower. Leaves				
				ois flower. Leaves out no more than				
			shoot o					
			shoot o 20% of	out no more than				
			shoot o 20% of flower	out no more than the length of the				
			shoot of 20% of flower mostly	out no more than the length of the and stalks are				
			shoot of 20% of flower mostly	but no more than the length of the and stalks are cut off directly the bottom site of				
Identification			shoot of 20% of flower mostly under	but no more than the length of the and stalks are cut off directly the bottom site of				
Identification Macroscopic bota	<i>nnical</i> V	isual	shoot of 20% of flower mostly under the flow	but no more than the length of the and stalks are cut off directly the bottom site of				
	<i>nnical</i> V	isual	shoot of 20% of flower mostly under the flow Brown flowers	but no more than the length of the and stalks are cut off directly the bottom site of wers , green clustered s of about 1.5 to	conform			
Macroscopic bota			shoot of 20% of flower mostly under the flow Brown flowers 3.0 cm	but no more than the length of the and stalks are cut off directly the bottom site of wers , green clustered s of about 1.5 to length				
<i>Macroscopic bota characters Microscopic bota</i>		isual 1onograph	shoot of 20% of flower mostly under the flow Brown flowers 3.0 cm Gland	but no more than the length of the and stalks are cut off directly the bottom site of wers , green clustered s of about 1.5 to length hairs are mainly	conform conform			
<i>Macroscopic bota characters Microscopic bota characters</i>	nical N	lonograph	shoot of 20% of flower mostly under the flow Brown flowers 3.0 cm Gland observ	but no more than the length of the and stalks are cut off directly the bottom site of wers , green clustered s of about 1.5 to length hairs are mainly ed	conform			
<i>Macroscopic bota characters Microscopic bota</i>	<i>nical</i> N tography P	1onograph h. Eur. (current ed.)	shoot of 20% of flower mostly under the flow Brown flowers 3.0 cm Gland observ	but no more than the length of the and stalks are cut off directly the bottom site of wers , green clustered s of about 1.5 to length hairs are mainly ed mparable with				
<i>Macroscopic bota characters Microscopic bota characters</i>	<i>nical</i> N tography P	lonograph	shoot of 20% of flower mostly under the flow Brown flowers 3.0 cm Gland observ	but no more than the length of the and stalks are cut off directly the bottom site of wers , green clustered s of about 1.5 to length hairs are mainly ed	conform			

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 NL-2515 XP THE HAGUE The Netherlands All correspondence addressed to the postal address quoting date and 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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Our reference 22I05EY22K30					
Foreign material	Visual	Free from insects other vermin		conf	orm
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram		<10 ²	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gram		<10 ¹	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gram)		conform	
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg
<i>Sum of aflatoxins B₁, B₂,</i> <i>G</i> 1 and <i>G</i> 2		≤ 4 µg/kg		< 4.0	µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2	2.8.13*	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	%	8.4	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	- 26.4]	18.6	%
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 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, 20 January 2023

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