



## Release certificate

Product:	<b>Cannabis flos, variety Bedrolite (hemp flowers), granulated</b>		
Country:	to be sold on the pharmaceutical market		
Strength:	tetrahydrocannabinol: < 1.0%	cannabidiol: ca. 7.5%	
Dosage form:	flowers		
Package size:	5 grams in container, 400 grams in bags		
Batch:	<b>23D17FR23J04</b>		
Order numbers:	containers: 385333 to 385334		
	bags: not applicable		
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam	harvest date/period: 17 April 2023	
Gamma irradiation:	Synergy Health Ede B.V. Soevereinstraat 2 NL-4879 NN Etten-Leur	date: 04 October 2023	dose: ≥ 10,0 kGy
Packager:	Fagron Nederland B.V. Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 17 October 2023 – 18 October 2023	
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel	1. General analysis Analysis number: 43705 Report date: 31 May 2023	2. Microbiology of end product in container Analysis number: 46531 Report date: 08 November 2023
Testing method:	OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021		

	Method	Specification	Result
Characters	Monograph	Odour characteristic for 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	conform
Identification			
<i>Macroscopic botanical characters</i>	Visual	Brown, green granulates of flowers of about 4 to 6 mm in diameter	conform
<i>Microscopic botanical characters</i>	Monograph	Gland hairs are mainly observed	conform
<i>Thin-layer chromatography</i>	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	conform
Foreign material	Visual	Free from insects and other vermin	conform



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Our reference

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Microbial contamination	Ph. Eur. (current ed.)		
<i>Total aerobic microbial count (TAMC)</i>	2.6.12, 2.6.13	$\leq 10^2$ cfu/gram	$< 10^2$ cfu/gram
<i>Total combined yeasts/moulds count (TYMC)</i>		$\leq 10^1$ cfu/gram	$< 10^1$ cfu/gram
<i>S. aureus, P. aeruginosa, bile-tolerant gram-negative bacteria</i>		Absent (1 gram)	conform
Aflatoxins	Monograph		
<i>Aflatoxin B<sub>1</sub></i>		$\leq 2$ µg/kg	$< 2.0$ µg/kg
<i>Sum of aflatoxins B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub></i>		$\leq 4$ µg/kg	$< 4.0$ µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	$\leq$ Limits Ph. Eur. 2.8.13*	conform
Heavy metals	Ph. Eur. (current ed.)		
<i>Lead</i>	2.4.27, 2.2.58	max. 20.0 ppm	$< 5$ ppm
<i>Cadmium</i>		max. 0.5 ppm	$< 0.125$ ppm
<i>Mercury</i>		max. 0.5 ppm	$< 0.125$ ppm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	$\leq 10.0$ %	8.6 %
Assay (HPLC)	Ph. Eur. (current ed.)		
<i>Tetrahydrocannabinol (THC, total equivalent)</i>	2.2.29, Monograph	$< 1.0$ %	0.3 %
<i>Cannabidiol (CBD, total equivalent)</i>		7.5 % [6.0 – 9.0]	8.2 %
Related substances (HPLC)	Ph. Eur. (current ed.)		
<i>Cannabinol (CBN, total equivalent)</i>	2.2.29, Monograph	$\leq 1.0$ %	$< 0.1$ %
Content of container	BMC-SWV 455	5 gram	$\pm 5.14$ gram
Expiry date			30 Sept. 2024

\*The following pesticides are not analysed: dithiocarbamates (expressed as CS<sub>2</sub>), methoxychlor, paraoxon-methyl 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, 27 November 2023

K. Amponsah / R.V. Goormachtigh  
QA, Office of Medicinal Cannabis