



## Release certificate

Product:	<b>Cannabis flos, variety Bedrobinol (hemp flowers)</b>		
Country:	to be sold on the pharmaceutical market		
Strength:	tetrahydrocannabinol: ca. 13.5%	cannabidiol: < 1.0%	
Dosage form:	flowers		
Package size:	5 grams in container, 400 grams in bags		
Batch:	<b>22K21FA23H30</b>		
Order numbers:	containers: 385139		
	bags: not applicable		
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam	harvest date/period: 21 November 2022	
Gamma irradiation:	Synergy Health Ede B.V. Soevereinstraat 2 NL-4879 NN Etten-Leur	date: 30 August 2023	dose: ≥ 10,0 kGy
Packager:	Fagron Nederland B.V. Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 11 September 2023	
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel	1. General analysis Analysis number: 41081 Report date: 03 January 2023	2. Microbiology of end product in container Analysis number: 45650 Report date: 21 September 2023
Testing method:	OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021		

	Method	Specification	Result
Characters	Monograph	Odour characteristic for 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	conform
Identification			
<i>Macroscopic botanical characters</i>	Visual	Brown, green clustered flowers of about 1.5 to 3.0 cm length	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



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Foreign material	Visual	Free from insects and other vermin	conform
Microbial contamination	Ph. Eur. (current ed.)		
<i>Total aerobic microbial count (TAMC)</i>	2.6.12, 2.6.13	≤ 10 <sup>2</sup> cfu/gram	< 10 <sup>2</sup> cfu/gram
<i>Total combined yeasts/moulds count (TYMC)</i>		≤ 10 <sup>1</sup> cfu/gram	< 10 <sup>1</sup> 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>		≤ 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>		≤ 4 µg/kg	< 4.0 µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ 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	≤ 10.0 %	9.0 %
Assay (HPLC)	Ph. Eur. (current ed.)		
<i>Tetrahydrocannabinol (THC, total equivalent)</i>	2.2.29, Monograph	13.5 % [10.8 – 16.2]	13.0 %
<i>Cannabidiol (CBD, total equivalent)</i>		<1.0 %	< 0.1 %
Related substances (HPLC)	Ph. Eur. (current ed.)		
<i>Cannabinol (CBN, total equivalent)</i>	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
Content of container	BMC-SWV 455	5 gram	± 5.15 gram
Expiry date			31 Aug. 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, 05 October 2023


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