



## Release certificate

**Product:** Cannabis flos, variety Bedrocan (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:** 22L26EY23D05  
**Order numbers:** containers: 384519 to 384528  
bags: 384532  
**Grower/drier:** Bedrocan Nederland B.V.          harvest date/period:  
P.O. Box 2009          26 December 2022  
NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health Ede B.V.          date:          dose:  
Soevereinstraat 2          05 April 2023          ≥ 10,0 kGy  
NL-4879 NN Etten-Leur  
**Packager:** Fagron B.V.          date:  
Venkelbaan 101          28 April 2023 – 11 May 2023  
NL-2908 KE Capelle a/d IJssel  
**Laboratory:** Laboratorium Ofichem B.V.          1. General analysis  
Heembadweg 5          Analysis number: 41621  
NL-9561 CZ Ter Apel          Report date: 06 Feb. 2023  
2. Microbiology of end product in container  
Analysis number: 43804  
Report date: 22 May 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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Our reference

22L26EY23D05

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 %	7.3 %
Assay (HPLC)	Ph. Eur. (current ed.)		
<i>Tetrahydrocannabinol (THC, total equivalent)</i>	2.2.29, Monograph	22 % [17.6 – 26.4]	21.5 %
<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 360	5 gram	± 5.15 gram
Expiry date			30 Apr. 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, 08 June 2023

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