



## Release certificate

**Product:** Cannabis flos, variety Bediol (hemp flowers), granulated  
**Country:** to be sold on the pharmaceutical market  
**Strength:** tetrahydrocannabinol: ca. 6.3% cannabidiol: ca. 8%  
**Dosage form:** flowers  
**Package size:** 5 grams in container, 400 grams in bags  
**Batch:** **22J31FB23B22**  
**Order numbers:** containers: 384212 and 384213  
bags: 384215  
**Grower/drier:** Bedrocan Nederland B.V. harvest date/period:  
P.O. Box 2009 31 October 2022  
NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health Ede B.V. date: dose:  
Soevereinstraat 2 22 February 2023  $\geq 10,0$  kGy  
NL-4879 NN Etten-Leur  
**Packager:** Fagron B.V. date:  
Venkelbaan 101 27 March 2023 – 30 March 2023  
NL-2908 KE Capelle a/d IJssel  
**Laboratory:** Laboratorium Ofichem B.V. 1. General analysis  
Heembadweg 5 Analysis number: 40630  
NL-9561 CZ Ter Apel Report date: 12 December 2022  
2. Microbiology of end product in container  
Analysis number: 43163  
Report date: 11 April 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	≤ 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 %	7.8 %
Assay (HPLC)	Ph. Eur. (current ed.)		
<i>Tetrahydrocannabinol (THC, total equivalent)</i>	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.3 %
<i>Cannabidiol (CBD, total equivalent)</i>		8.0 % [6.4 – 9.6]	8.6 %
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			29 Feb. 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, 19 April 2023


 Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis

Dr. M.J. van de Velde