



## Release certificate

Product: **Cannabis flos, variety Bedrobinol (hemp flowers)**  
Country: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: approx. 13.5 %                          cannabidiol : <1.0%  
Dosage form: flowers  
Package size: 5 grams in container, 400 grams in bags  
Batch: **21B22FA21E05**  
Order numbers: containers: 377777 to 377779  
                        bags:       not available  
Grower/drier: Bedrocan B.V.    harvest date/period:  
                    P.O. Box 2009    22 February 2021  
                    NL- 9640 CA Veendam  
Gamma irradiation: Synergy Health Ede B.V.                      date:    dose:  
                                Soevereinstraat 2                                5 May 2021                                      ≥ 10,0 kGy  
                                NL-4879 NN Etten-Leur  
Packager:            Fagron B.V.    date:  
                                Venkelbaan 101    18 – 20 May 2021  
                                NL-2908 KE Capelle a/d IJssel  
Laboratory:        Laboratorium Ofichem B.V.        1.    General analysis  
                                Heembadweg 5    Analysis number: 28438  
                                NL-9561 CZ Ter Apel    Report date: 6 April 2021  
  2.    Microbiology of end product in container  
  Analysis number: 30149  
  Report date: 4 June 2021  
Testing method:    Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014

	Method	Specification	Result
Appearance	monograph	brown green clustered flowers of 1,5 to 3 cm with a characteristic smell	conform
Identity			
<i>microscopy</i>	monograph	mainly gland hairs visible	conform
<i>thin layer chromatography</i>	monograph	monograph	conform
Foreign material	monograph	insects and other vermin are absent	conform
Fineness	monograph	<ul style="list-style-type: none"><li>• no leaves shooting out more than 20% of the length of the flowers</li><li>• stalks are cut away directly under the bottom flowers of the inflorescence</li></ul>	conform

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Microbiological purity	Ph. Eur (current ed.) 5.1.4.		
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 <sup>2</sup> cfu/gram	< 10 <sup>2</sup> cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 <sup>1</sup> cfu/gram	< 10 <sup>1</sup> cfu/gram
<i>P. aeruginosa, S.aureus and Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent	conform
Absence of aflatoxins	Ph. Eur (current ed.) "Determination of aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	≤ 4 µg/kg	< 4.0 µg/kg
Absence of pesticides	Ph. Eur (current ed.) "Pesticide residues" (2.8.13)	≤ Limits Ph. Eur 2.8.13*	conform
Absence of heavy metals	Ph. Eur (current ed.) "Heavy metals in herbal drugs and fatty oils" (monograph)	max. 20.0 ppm max. 0.5 ppm max. 0.5 ppm	< 5 ppm < 0.125 ppm < 0.125 ppm
<i>lead</i>			
<i>mercury</i>			
<i>cadmium</i>			
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤ 10.0 %	8.6 %
Assay (HPLC)			
<i>tetrahydrocannabinol(THC)</i>	monograph	approx. 13.5 %	15.0 %
<i>cannabidiol (CBD)</i>	monograph	< 1.0 %	< 0.1 %
Related substances (HPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	< 0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.15 gram
Expiry date			05 / 2022

\*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, 21 June 2021

**Dr. M.J. van de Velde**

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head, Office of Medicinal Cannabis