



## Release certificate

Product:	<b>Cannabis flos, variety Bedica (hemp flowers), granulated</b>		
Country:	to be sold on the pharmaceutical market		
Strength:	tetrahydrocannabinol: approx. 14%	cannabidiol: <1.0%	
Dosage form:	Flowers		
Package size:	5 grams in container, 400 grams in bags		
Batch:	<b>21E10FP21F30</b>		
Order numbers:	containers: 378640, 378853 and 378854 bags: 378642		
Grower/drier:	Bedrocan BV P.O. Box 2009 NL- 9640 CA Veendam	harvest date/period: 10 May 2021	
Gamma irradiation:	Synergy Health Ede B.V. Soevereinstraat 2 NL-4879 NN Etten-Leur	date: 30 June 2021	dose: ≥ 10,0 kGy
Packager:	Fagron BV Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 2 – 6 August 2021	
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel	1. General analysis Analysis number: 30115 Report date: 25 June 2021 2. Microbiology of end product in container Analysis number: 31811 Report date: 27 August 2021	
Testing method:	Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014		

	Method	Specification	Result
Appearance	monograph	brown green granulated material of the flowers (about 5 mm) 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	stalks are not longer than 2,0 cm and only 20% of the stalks is between 1,5 and 2,0 cm.	conform



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 metal <i>lead</i> <i>mercury</i> <i>cadmium</i>	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
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0 %	8.0 %
Assay (HPLC)			
<i>tetrahydrocannabinol(THC)</i>	monograph	approx. 14 %	14.4 %
<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	± 5.14 gram
Expiry date			06 / 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, 30 August 2021

  
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head, Office of Medicinal Cannabis