



## Release certificate

Product: **Cannabis flos, variety Bedrocan (hemp flowers)**  
Country: to be sold on the pharmaceutical market  
Strength: tetrahydrocannabinol: approx. 22%      cannabidiol : <1.0%  
Dosage form: Flowers  
Package size: 5 grams in container, 400 grams in bags  
Batch: **18J29EY19B12**  
Order numbers:      containers: 357591 to 357601  
   bags: not available  
Grower/drier:      Bedrocan BV      harvest date/period:  
                                 P.O. Box 2009      29 October 2018  
                                 NL- 9640 CA Veendam  
Gamma irradiation:      Synergy Health      date:      dose:  
                                 Soeverinstraat 2      12 Feb. 2019      ≥ 10,0 kGy  
                                 NL-4879 NN Etten-Leur  
Packager:      Fagron BV      date:  
                                 Venkelbaan 101      27 March – 3 April 2019  
                                 NL-2908 KE Capelle a/d IJssel  
Part of analysis:      1.general analysis      2.microbiology of end product in  
                                 container  
Laboratories:      1. PROXY Laboratories BV      2. Bactimm BV  
                                 Archimedesweg 25      Middenkampweg 17  
                                 NL-2333 CM Leiden      NL-6545 CH Nijmegen  
Analysis number:      1. 394-0112001      2. 04.066  
Report date:      1. 11 December 2018      2. 10 April 2019  
Testing method:      Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014  
End check:      Office of Medicinal Cannabis      date: 12 April 2019

	<b>Method</b>	<b>Specification</b>	<b>Result</b>
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</i>	monograph	monograph	conform
<i>chromatography</i>			
Foreign material	monograph	stalks, 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



	Method	Specification	Result
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 cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤10 cfu/gram	< 10 cfu/gram
<i>P. aeruginosa, S.aureus and Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent	conform
Absence of aflatoxines	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	< 2.2 µg/kg
Absence of pesticides	monograph	Ph. Eur (current ed.) 2.8.13	conform
Absence of heavy metal			
<i>lead</i>	Ph. Eur (current ed.)	max. 20.0 ppm	1.33 ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	< 0.1 ppm
<i>cadmium</i>		max. 0.5 ppm	0.15 ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0 %	8.7 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>tetrahydrocannabinol (THC)</i>	monograph	approx. 22 %	20.5 %
<i>cannabidiol (CBD)</i>	monograph	<1.0 %	0.1 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5,10 gram
Expiry date			02 / 2020

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, 15 April 2019

Dr. M.J. van de Velde

head, Office of Medicinal Cannabis

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