



## 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:** 19B18EY19F04  
**Order numbers:** containers: 361460 to 361466  
    bags: not available  
**Grower/drier:** Bedrocan BV      harvest date/period:  
    P.O. Box 2009      18 February 2019  
    NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health      date:      dose:  
    Soeverestraat 2      4 June 2019      ≥ 10,0 kGy  
    NL-4879 NN Etten-Leur  
**Packager:** Fagron BV      date:  
    Venkelbaan 101      25 – 30 August 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. 394-0112322      2. AAE21781  
**Report date:** 1. 20 December 2018      2. 5 September 2019  
**Testing method:** Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014  
**End check:** Office of Medicinal Cannabis      date: 10 September 2019

	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</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.	$\leq 10^2$ cfu/gram	< 10 cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	$\leq 10$ 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	1.5 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	< 0.1 ppm
Loss on drying	Ph. Eur (current ed.)	$\leq 10.0$ %	9.3 %
	"Loss on drying" meth. C (2.2.32)		
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>tetrahydrocannabinol (THC)</i>	monograph	approx. 22 %	21.5 %
<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	± 5,12 gram
Expiry date			05 / 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, 12 September 2019

Dr. M.J. van de Velde

head, Office of Medicinal Cannabis

Dr. M.J. van de Velde