



## Release certificate

**Product:** Cannabis flos, variety Bediol (hemp flowers), granulated  
**Country:** to be sold on the pharmaceutical market  
**Strength:** tetrahydrocannabinol: approx. 6.3%      cannabidiol: approx. 8%  
**Dosage form:** flowers  
**Package size:** 5 grams in container  
**Batch:** 18J01FB18J24  
**Order numbers:** containers: 354266 to 345268  
**Grower/drier:** Bedrocan BV      harvest date/period:  
                          P.O. Box 2009      1 October 2018  
                          NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health      date:      dose:  
                          Soevereinstraat 2      24 October 2018      ≥ 10,0 kGy  
                          NL-4879 NN Etten-Leur  
**Packager:** Fagron BV      date:  
                          Venkelbaan 101      13 – 14 November 2018  
                          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. 394-0111494      2. 14.643  
**Report date:** 1. 28 November 2018      2. 26 November 2018  
**Testing method:** Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014  
**End check:** Office of Medicinal Cannabis      date: 16 November 2018

	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	stalks, insects and other vermin are absent	conform
Fineness	monograph	fine granulated flowers without stalks longer than 1,0 – 1,5 cm	conform
Microbiological purity	Ph. Eur (current ed.)		



	Method	Specification	Result
	5.1.4.		
Total aerobic microbial count (TAMC)	5.1.4.-1.	$\leq 10^2$ cfu/gram	< 10 cfu/gram
Total yeast and moulds count (TYMC)	5.1.4.-1.	$\leq 10$ cfu/gram	< 10 cfu/gram
<i>P. aeruginosa</i> , <i>S. aureus</i> and Bile tolerant gram neg bacteria	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 $\mu$ g/kg	< 2.2 $\mu$ g/kg
Absence of pesticides	monograph	Ph. Eur (current ed.) 2.8.13	conform
Absence of heavy metals			
lead	Ph. Eur (current ed.)	max. 20.0 ppm	< 0.5 ppm
mercury	"Heavy metals in	max. 0.5 ppm	< 0.1 ppm
cadmium	herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	< 0.1 ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	$\leq 10.0$ %	8.0 %
Assay (UPLC)			
fingerprint	monograph	similar	conform
tetrahydrocannabinol(THC)	monograph	approx. 6.3 %	6.9 %
cannabidiol (CBD)	monograph	approx. 8 %	9.6 %
Related substances (UPLC)			
cannabinol (CBN)	monograph	< 1.0 %	0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	$\pm 5.09$ gram
Expiry date			10 / 2019

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, 28 November 2018

  
 Dr. M.J. van de Velde  
 head, Office of Medicinal Cannabis