



## Release certificate

Product: **Cannabis flos, variety Bedica (hemp flowers), granulated**  
 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: **19J28FP19L17**  
 Order numbers: Containers: 366660 to 366661  
 Bags: 366659  
 Grower/drier: Bedrocan BV      harvest date/period:  
 P.O. Box 2009      28 October 2019  
 NL- 9640 CA Veendam  
 Gamma irradiation: Synergy Health      date:      dose:  
 Soeverinstraat 2      19 December 2019      ≥ 10,0 kGy  
 NL-4879 NN Etten-Leur  
 Packager: Fagron BV      date:  
 Venkelbaan 101      9 – 13 January 2020  
 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. 394-0117625      2. AAF96880  
 Report date: 1. 21 January 2020      2. 21 January 2020  
 Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014  
 End check: Office of Medicinal Cannabis      date: 24 January 2020

	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</i>	monograph	monograph	conform
<i>chromatography</i>			
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



	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 metals			
<i>lead</i>	Ph. Eur (current ed.)	max. 20.0 ppm	1.19 ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	< 0.05 ppm
<i>cadmium</i>		max. 0.5 ppm	0.12 ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0 %	7.9 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 14 %	16.5 %
<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	± 5.14 gram
Expiry date			12 / 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, 27 January 2020

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