



## Release certificate

**Product:** Cannabis flos, variety Bedica (hemp flowers), granulated  
**Country:** to be sold on the pharmaceutical market  
**Strength:** dronabinol: approx. 14% cannabidiol: <1.0%  
**Dosage form:** flowers  
**Package size:** 5 grams in container  
**Batch:** 15G27FP15H13  
**Order numbers:** 310602 to 310611  
**Grower/drier:** Bedrocan BV harvest date/period:  
P.O. Box 2009 27 July 2015  
NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health date: dose:  
Soeverinstraat 2 12 August 2015 ≥ 10,0 kGy  
NL-4879 NN Etten-Leur  
**Packager:** Fagron BV date:  
Venkelbaan 101 17 – 23 September 2015  
NL-2908 KE Capelle a/d IJssel  
**Part of analysis:** 1.general analysis 2.microbiology of end product in  
container  
**Laboratories:** 1. Farmalyse BV 2. Bactimm BV  
Pieter Liefinckweg 2 Middenkampweg 17  
NL-1505 HX Zaandam NL-6545 CH Nijmegen  
**Analysis number:** 1. 394-1508-0957 2. 15.951  
**Report date:** 1. 15 September 2015 2. 29 September 2015  
**Testing method:** Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014  
**End check:** Office of Medicinal Cannabis date: 30 September 2015

	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



	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 ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	< 0.5 ppm
<i>cadmium</i>		max. 0.5 ppm	< 0.1 ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0 %	6.0 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 14 %	16.1 %
<i>cannabidiol (CBD)</i>	monograph	<1.0 %	0.1 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	<1.0 %	< 0.05 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.03 gram
Expiry date			08 / 2016

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, 2 October 2015

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