



## Release certificate

**Product:** Cannabis flos, variety **Bedropuur (hemp flowers)**  
**Country:** to be sold on the pharmaceutical market  
**Strength:** dronabinol: approx. 23%                      cannabidiol : <1.0%  
**Dosage form:** flowers  
**Package size:** 250 grams in bags  
**Batch:** **13K11FS13L10**  
**Order numbers:** 290289 and 290293  
**Grower/drier:** Bedrocan BV    harvest date/period:  
P.O. Box 2009    11 November 2013  
NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health    date:                      dose:  
Soevereinstraat 2    10 December 2013                      ≥ 10,0 kGy  
NL-4879 NN Etten-Leur  
**Packager:** Fagron BV    date:  
Venkelbaan 101    7 February 2014  
NL-2908 KE Capelle a/d IJssel  
**Part of analysis:** 1.general analysis    2.microbiology of end product  
**Laboratories:** 1. Farmalyse BV    2. Bactimm BV  
Pieter Liefinckweg 2    Middenkampweg 17  
NL-1505 HX Zaandam    NL-6545 CH Nijmegen  
**Analysis number:** 1. 394-1312-2060    2. 20.404  
**Report date:** 1. 8 January 2014    2. 24 December 2013  
**Testing method:** Analytical monograph by BMC / Farmalyse, version 7.0, Oct. 31, 2013  
**End check:** Office of Medicinal Cannabis    date: 6 February 2014

	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 then 20% of the length of the flowers</li><li>stalks are cut away directly under the bottom flowers of the inflorescence</li></ul>	conform

Ministry of Health, Welfare and Sport

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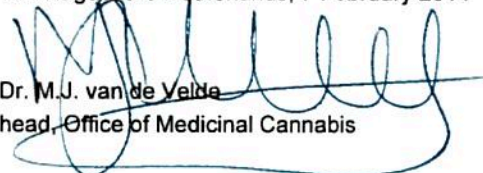
Our reference

13K11FS13L10

	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	< 1.0 ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	0.01 ppm
<i>cadmium</i>		max. 0.5 ppm	< 0.05 ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0 %	6.4 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 23 %	23.3 %
<i>cannabidiol (CBD)</i>	monograph	<1.0 %	0.1 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	< 0.1 %
Expiry date			12 / 2014

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, 7 February 2014

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