



## Release certificate

**Product:** Cannabis flos, variety Bedrobinol (hemp flowers)  
**Country:** to be sold on the pharmaceutical market  
**Strength:** dronabinol: approx. 13.5 %                      cannabidiol: <1.0%  
**Dosage form:** flowers  
**Package size:** 5 grams in containers  
**Batch:** **15B09FA15B24**  
**Order numbers:** 304514 to 304522  
**Grower/drier:** Bedrocan BV    harvest date/period:  
                          P.O. Box 2009    9 February 2015  
                          NL- 9640 CA Veendam  
**Gamma irradiation:** Synergy Health    date:                      dose:  
                          Soeverinstraat 2    24 February 2015                      ≥ 10,0 kGy  
                          NL-4879 NN Etten-Leur  
**Packager:** Fagron BV    date:  
                          Venkelbaan 101    22 - 29 April 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 Liefstinckweg 2    Middenkampweg 17  
                             NL-1505 HX Zaandam    NL-6545 CH Nijmegen  
**Analysis number:** 1. 394-1502-0248    2. 06.916  
**Report date:** 1. 13 April 2015    2. 8 May 2015  
**Testing method:** Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014  
**End check:** Office of Medicinal Cannabis    date: 24 April 2015

	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

	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 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	< 0.1 ppm
<i>cadmium</i>		max. 0.5 ppm	< 0.1 ppm
Loss on drying	Ph. Eur (current ed.)	$\leq 10.0$ %	7.8 %
	"Loss on drying" meth. C (2.2.32)		
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 13.5 %	16.3 %
<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	± 5.02 gram
Expiry date			02 / 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, 8 May 2015

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