



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 container
Batch: **13G15FA13H06**
Label numbers: 284534 to 284538
Grower/drier: Bedrocan BV harvest date/period:
 P.O. Box 2009 22 July 2013
 NL- 9640 CA Veendam
Gamma irradiation: Synergy Health date: dose:
 Soeverinstraat 2 6 August 2013 ≥ 10,0 kGy
 NL-4879 NN Etten-Leur
Packager: Fagron BV date:
 Venkelbaan 101 3 – 10 September 2013
 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. VWS 1308 / 1373 2. 14.916
Report date: 1. 23 August 2013 2. 16 September 2013
Testing method: Analytical monograph by BMC / Farmalyse, version 6.2, Oct. 20, 2010
End check: Office of Medicinal Cannabis date: 25 September 2013

	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"> • no leaves shooting out more then 20% of the length of the flowers • stalks are cut away directly under the bottom flowers of the inflorescence 	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 ² 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 pesticides*	monograph	Ph. Eur (current ed.) 2.8.13	not assessed
Absence of heavy metals*			
<i>lead*</i>	Ph. Eur (current ed.)	max. 20.0 ppm	not assessed
<i>mercury*</i>	"Heavy metals in	max. 0.5 ppm	not assessed
<i>cadmium*</i>	herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	not assessed
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0 %	8.6 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 13.5 %	14.8 %
<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			08 / 2014

* These contents are tested regularly, at random, approximately once a year.

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, 26 September 2013

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