



Release certificate

Product: Cannabis flos, variety Bediol (hemp flowers), granulated
Country: to be sold on the pharmaceutical market
Strength: dronabinol: approx. 6.3% cannabidiol: approx. 8%
Dosage form: flowers
Package size: 5 grams in container, 50 grams in bags
Batch: 15K02FB15K24
Order numbers: containers: 314288 to 314295
bags: 314287
Grower/drier: Bedrocan BV harvest date/period:
P.O. Box 2009 2 November 2015
NL- 9640 CA Veendam
Gamma irradiation: Synergy Health date: dose:
Soeverinstraat 2 24 November 2015 ≥ 10,0 kGy
NL-4879 NN Etten-Leur
Packager: Fagron BV date:
Venkelbaan 101 21 – 28 December 2015
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. 394-0087169 2. 21.368
Report date: 1. 18 December 2015 2. 4 January 2016
Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014
End check: Office of Medicinal Cannabis date: 30 December 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.	$\leq 10^2$ 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 aflatoxines	Ph.Eur (current ed.) "Determination of aflatoxins B ₁ , B ₂ , G ₁ and G ₂ in herbal drugs" (2.8.18)	< 4 µg/kg	1.3 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.) "Loss on drying" meth. C (2.2.32)	≤ 10.0 %	8.5 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 6.3 %	7.0 %
<i>cannabidiol (CBD)</i>	monograph	approx. 8 %	9.3 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.00 gram
Expiry date			11 / 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, 4 January 2015

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