

Ministry of Health, Welfare and Sport Office of Medicinal Cannabis

## Release certificate

Product: Cannabis flos, variety Bedrocan (hemp flowers)

Country: to be sold on the pharmaceutical market

Strength: dronabinol: approx. 22% cannabidiol: <1.0%

Dosage form: flowers

Package size: 5 grams in container Batch: 16H22EY16I06

Order numbers: 324913 to 324923

Grower/drier: Bedrocan BV harvest date/period: P.O. Box 2009 22 August 2016

NL- 9640 CA Veendam

Gamma irradiation: Synergy Health date: dose: Soevereinstraat 2 6 September 2016 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron BV

12 - 17 October 2016 Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Part of analysis: 1.general analysis 2.microbiology of end product in

Laboratories: PROXY Laboratories BV Bactimm BV

Archimedesweg 25 Middenkampweg 17 NL-2333 CM Leiden NL-6545 CH Nijmegen

container

Analysis number: 1. 394-0093239 2.17.390

Report date: 1. 12 September 2016 2. 24 October 2016 Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014

End check: Office of Medicinal Cannabis date: 26 October 2016

Appearance	<b>Method</b> monograph	Specification brown green clustered flowers of 1,5 to 3 cm with a characteristic smell	Result conform
Identity			
microscopy	monograph	mainly gland hairs visible	conform
thin layer chromatography	monograph	monograph	conform
Foreign material	monograph	stalks, insects and other vermin are absent	conform
Fineness	monograph	<ul> <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

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## Ministry of Health, Welfare and Sport

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	Method	Specific	ation	Res	ult
Microbiological purity	Ph. Eur (current ed.)				
	5.1.4.				
Total aerobic microbial count (TAMC)	5,1.4,-1.	≤10 <sup>2</sup> cfu/gram		< 10	cfu/gram
Total yeast and moulds count (TYMC)	5.1.41.	≤10 cfu/gram		< 10	cfu/gram
P. aeruginosa,	5.1.41.				
S.aureus and Bile tolerant gram neg bacteria		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		n.a.
Absence of heavy metal					
lead	Ph. Eur (current ed.)	max. 20.0	ppm	< 1	ppm
mercury	"Heavy metals in	max. 0.5	ppm	< 0.1	ppm
cadmium	herbal drugs and fatty oils" (monograph)	max. 0.5	ppm	< 0.1	ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%	10.0	%
Assay (UPLC)					
fingerprint	monograph	simila	ar		conform
dronabinol (THC)	monograph	approx. 22	%	24.3	%
cannabidiol (CBD)	monograph	<1.0	%	0.1	%
Related substances (UPLC)					
cannabinol (CBN)	monograph	< 1.0	%	0.1	%
Content of container Expiry date	BMC-SWV 320	approx. 5	gram	± 5.04	gram 2017

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, 31 October 2016

Dr. M.J van de Velde

head, Office of Medicinal Cannabis