

## Office of Medicinal Cannabis



## Release certificate

Product:

Cannabis flos, variety Bediol (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

dronabinol: approx. 6.3%

Dosage form: flowers

5 grams in container, 50 grams in bags

Package size: Batch:

14J13FB14K19

Order numbers:

containers:

300169 to 300175

bags:

300176

Grower/drier:

Bedrocan BV

P.O. Box 2009

13 October 2014

cannabidiol: approx. 8%

NL-9640 CA Veendam

Gamma irradiation:

Synergy Health

date:

dose:

Soevereinstraat 2

19 November 2014 ≥ 10,0 kGy

harvest date/period:

NL-4879 NN Etten-Leur

Packager:

Fagron BV

date:

Venkelbaan 101

4 - 8 December 2014

NL-2908 KE Capelle a/d IJssel

Part of analysis:

1.general analysis

2.microbiology of end product in

container

Laboratories:

Farmalyse BV

Bactimm BV

Pieter Lieftinckweg 2

Middenkampweg 17 NL-6545 CH Nijmegen

NL-1505 HX Zaandam

Analysis number:

1. 394-1411-1449

2. 22.898

Report date:

1. 10 December 2014

2. 15 December 2014 Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014

Testing method: End check:

Office of Medicinal Cannabis

date: 11 December 2014

Appearance	<b>Method</b> monograph	Specification brown green granulated material of the flowers (about 5 mm) with a characteristic smell	Result conform
Identity microscopy thin layer chromatography	monograph monograph	mainly gland hairs visible monograph	conform 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

## Ministry of Health, Welfare and Sport

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	Method	Specifi	ication	R	esult
Microbiological purity	Ph. Eur (current ed.) 5.1.4.				
Total aerobic microbial count (TAMC)	5.1.41.	≤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, S.aureus and Bile tolerant gram neg bacteria	5.1.41.	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 (curren	nt ed.) 2.8.13		conform
Absence of heavy metals	Die Control of N	22.2		- 1	
lead mercury	Ph. Eur (current ed.) "Heavy metals in	max. 20.0 max. 0.5	• •	< 1 < 0.1	ppm
cadmium	herbal drugs and fatty oils" (monograph)	max. 0.5		< 0.1	
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%	7.1	%
Assay (UPLC)					
fingerprint	monograph		nilar		onform
dronabinol (THC)	monograph	approx. 6.3		6.3	
cannabidiol (CBD) Related substances (UPLC)	monograph	approx. 8	%	8.2	%
cannabinol (CBN)	monograph	< 1.0	%	0.1	%
Content of container Expiry date	BMC-SWV 320	approx. 5	gram	± 5.03	gram 2015

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, 15 December 2014

Dr. M.J. van de Velde

head, Office of Medicinal Cannabis