



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:	16C28FB16D20		
Order numbers:	Containers: 319371 to 319377 Bags: 319370		
Grower/drier:	Bedrocan BV P.O. Box 2009 NL- 9640 CA Veendam	harvest date/period: 28 March 2016	
Gamma irradiation:	Synergy Health Soeverinstraat 2 NL-4879 NN Etten-Leur	date: 20 April 2016	dose: ≥ 10,0 kGy
Packager:	Fagron BV Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 24 May 2016 to 26 May 2016 and 22 April 2016	
Part of analysis:	1.general analysis	2.microbiology of end product in container	
Laboratories:	1. PROXY Laboratories BV Archimedesweg 25 NL-2333 CM Leiden	2. Bactimm BV Middenkampweg 17 NL-6545 CH Nijmegen	
Analysis number:	1. 394-0090264	2. 08.239	
Report date:	1. 23 May 2016	2. 30 May 2016	
Testing method:	Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014		
End check:	Office of Medicinal Cannabis	date:1 June 2016 and 26 April 2016	

	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</i>	monograph	monograph	conform
<i>chromatography</i>			
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 μ g/kg	< 2.2 μ g/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	<2 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 %	7.5 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 6.3 %	6.4 %
<i>cannabidiol (CBD)</i>	monograph	approx. 8 %	7.8 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.06 gram
Expiry date			04 / 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, 6 June 2016

Dr. M.J. van de Velde

head, Office of Medicinal Cannabis