



Release certificate

Product:	Cannabis flos, variety Bedica (hemp flowers), granulated		
Country:	to be sold on the pharmaceutical market		
Strength:	dronabinol: approx. 14%	cannabidiol:	<1.0%
Dosage form:	flowers		
Package size:	5 grams in container		
Batch:	16J10FP17A25		
Order numbers:	330052 to 330056		
Grower/drier:	Bedrocan BV	harvest date/period:	
	P.O. Box 2009	10 October 2016	
	NL- 9640 CA Veendam		
Gamma irradiation:	Synergy Health	date:	dose:
	Soevereinstraat 2	25 January 2017	≥ 10,0 kGy
	NL-4879 NN Etten-Leur		
Packager:	Fagron BV	date:	
	Venkelbaan 101	14 – 16 February 2017	
	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. 394-0094651	2. 03.543	
Report date:	1. 8 December 2016	2. 27 January 2017	
Testing method:	Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014		
End check:	Office of Medicinal Cannabis	date: 22 February 2017	

	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.	≤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	< 2.2 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 %	8.2 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 14 %	15 %
<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	± 5.08 gram
Expiry date			01 / 2018

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, 27 February 2017

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