



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, 250 grams in bags
Batch: 16F20EY17E16
Order numbers: 333856 to 333860
Grower/drier: Bedrocan BV harvest date/period:
 P.O. Box 2009 20 June 2016
 NL- 9640 CA Veendam
Gamma irradiation: Synergy Health date: dose:
 Soevereinstraat 2 16 May 2017 ≥ 10,0 kGy
 NL-4879 NN Etten-Leur
Packager: Fagron BV date:
 Venkelbaan 101 10 – 14 August 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. 394-0092040 2. 16.363
Report date: 1. 23 November 2016 2. 21 August 2017
Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014
End check: Office of Medicinal Cannabis date: 30 August 2017

	Method	Specification	Result
Appearance	monograph	brown green clustered flowers of 1,5 to 3 cm 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	<ul style="list-style-type: none"> no leaves shooting out more then 20% of the length of the flowers stalks are cut away directly under the bottom flowers of the inflorescence 	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	15 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 metal			
<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	< 0.5 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 %	10.0 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>dronabinol (THC)</i>	monograph	approx. 22 %	19.3 %
<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	5.10 gram
Expiry date			05 / 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, 31 August 2017


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