



Release certificate

Product: Cannabis flos, variety Bediol (hemp flowers), granulated
Country: to be sold on the pharmaceutical market
Strength: tetrahydrocannabinol: approx. 6.3% cannabidiol: approx. 8%
Dosage form: flowers
Package size: 5 grams in container, 400 grams in bags
Batch: 19C11FB19118
Order numbers: containers: 363998 to 363999
 bags: 363997
Grower/drier: Bedrocan BV harvest date/period:
 P.O. Box 2009 11 March 2019
 NL- 9640 CA Veendam
Gamma irradiation: Synergy Health date: dose:
 Soeverinstraat 2 18 September 2019 ≥ 10,0 kGy
 NL-4879 NN Etten-Leur
Packager: Fagron BV date:
 Venkelbaan 101 24 – 25 October 2019
 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. 394-0114335 2. AAF10559
Report date: 1. 19 July 2019 2. 14 November 2019
Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014
End check: Office of Medicinal Cannabis date: 8 November 2019

	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 chromatography</i>	monograph	monograph	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



	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	< 0.5 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 %	6.5 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>tetrahydrocannabinol(THC)</i>	monograph	approx. 6.3 %	7.3 %
<i>cannabidiol (CBD)</i>	monograph	approx. 8 %	8.9 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.12 gram
Expiry date			09 / 2020

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, 14 November 2019

Dr. M.J. van de Velde

Dr. M.J. van de Velde

head, Office of Medicinal Cannabis