



Release certificate

Product: Cannabis flos, variety Bedrocan (hemp flowers)
Country: to be sold on the pharmaceutical market
Strength: tetrahydrocannabinol: approx. 22% cannabidiol : <1.0%
Dosage form: Flowers
Package size: 5 grams in container, 400 grams in bags
Batch: 18B26EY19A09
Order numbers: containers: 356473 to 356481 and 356617, 356618
 bags: not available
Grower/drier: Bedrocan BV harvest date/period:
 P.O. Box 2009 26 February 2018
 NL- 9640 CA Veendam
Gamma irradiation: Synergy Health date: dose:
 Soeverestraat 2 9 January 2019 ≥ 10,0 kGy
 NL-4879 NN Etten-Leur
Packager: Fagron BV date:
 Venkelbaan 101 5 – 12 March 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. 394-0106712 2. 03.090
Report date: 1. 24 April 2018 2. 18 March 2019
Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014
End check: Office of Medicinal Cannabis date: 18 March 2019

	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 than 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.	$\leq 10^2$ 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 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	1.2 ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils"	max. 0.5 ppm	< 0.1 ppm
<i>cadmium</i>	(monograph)	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. 22 %	22.7 %
<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	± 5,12 gram
Expiry date			01 / 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, 19 March 2019

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