



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: **19E27FB20F03**
 Order numbers: containers: 371518 and 370727
 bags: not available
 Grower/drier: Bedrocan BV harvest date/period:
 P.O. Box 2009 27 May 2019
 NL- 9640 CA Veendam
 Gamma irradiation: Synergy Health date: dose:
 Soeverinstraat 2 3 June 2020 ≥ 10,0 kGy
 NL-4879 NN Etten-Leur
 Packager: Fagron BV date:
 Venkelbaan 101 8 and 9 July 2020
 NL-2908 KE Capelle a/d IJssel
 Laboratory: PROXY Laboratories BV Laboratorium Ofichem BV Laboratorium Ofichem BV
 Archimedesweg 25 Heembadweg 5 Heembadweg 5
 NL-2333 CM Leiden NL-9561 CZ Ter Apel NL-9561 CZ Ter Apel
 Analysis: General analysis Pesticides Microbiology of end product in container
 Analysis number: 394-0115553 25645 25195
 Report date: 2 August 2019 31 August 2020 21 July 2020
 Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014

	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 2.0 cm. Only 20% of the stalks is between 1.5 and 2.0 cm	conform



	Method	Specification	Result
	Ph. Eur (current ed.) 5.1.4.		
Microbiological purity			
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤10 ² cfu/gram	< 33 cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤10 cfu/gram	< 7 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	≤ Limits Ph. Eur 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 %	8.3 %
Assay (UPLC)			
<i>fingerprint</i>	monograph	similar	conform
<i>tetrahydrocannabinol(THC)</i>	monograph	approx. 6.3 %	6.6 %
<i>cannabidiol (CBD)</i>	monograph	approx. 8 %	8.8 %
Related substances (UPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.15 gram
Expiry date			06 / 2021

*The following pesticides are not analysed: dithiocarbamates (expressed as CS₂), methoxychlor, paraoxon-methyl and tetradifon. The limit of detection is increased for fenprothrin to 0.1 mg/kg and azinphos-ethyl to 1 mg/kg.

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, 2 September 2020

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

Dr. M.J. van de Velde