



## Release certificate

**Product:** Cannabis flos, variety Bedica (hemp flowers), granulated  
**Country:** to be sold on the pharmaceutical market  
**Strength:** tetrahydrocannabinol: approx. 14%      cannabidiol: <1.0%  
**Dosage form:** Flowers  
**Package size:** 5 grams in container, 400 grams in bags  
**Batch:** 20C02FP20D15  
**Order numbers:** Containers: 369525 to 369527  
 Bags: 369524  
**Grower/drier:** Bedrocan BV  
 P.O. Box 2009  
 NL- 9640 CA Veendam      harvest date/period:  
 2 March 2020  
**Gamma irradiation:** Synergy Health      date:      dose:  
 Soevereinstraat 2      15 April 2020      ≥ 10,0 kGy  
 NL-4879 NN Etten-Leur  
**Packager:** Fagron BV      date:  
 Venkelbaan 101      24 – 29 April 2020  
 NL-2908 KE Capelle a/d IJssel  
**Part of analysis:** 1. general analysis      2. microbiology of end product in container  
**Laboratories:** 1. Laboratorium Ofichem B.V.      2. Bactimm B.V.  
 Heembadweg 5      Middenkampweg 17  
 NL-9561 CZ Ter Apel      NL-6545 CH Nijmegen  
**Analysis number:** 1. 23361      2. AAH70160  
**Report date:** 1. 30 June 2020      2. 13 May 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</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



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.	$\leq 10$ 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 <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> and G <sub>2</sub> in herbal drugs" (2.8.18)	$\leq 4$ µg/kg	$\leq 4.0$	µg/kg
Absence of pesticides	Ph. Eur (current ed.) "Pesticide residues" (2.8.13)	$\leq$ Limits Ph. Eur 2.8.13*		conform
Absence of heavy metals				
<i>lead</i>	Ph. Eur (current ed.)	max. 20.0 ppm	< 5	ppm
<i>mercury</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 0.5 ppm	< 0.125	ppm
<i>cadmium</i>		max. 0.5 ppm	< 0.125	ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	$\leq 10.0$ %	7.8	%
Assay (HPLC)				
<i>tetrahydrocannabinol(THC)</i>	monograph	approx. 14 %	14.7	%
<i>cannabidiol (CBD)</i>	monograph	$\leq 1.0$ %	< 0.1	%
Related substances (HPLC)				
<i>cannabinol (CBN)</i>	monograph	$\leq 1.0$ %	< 0.1	%
Content of container	BMC-SWV 320	approx. 5 gram	$\pm 5.14$	gram
Expiry date			04 /	2021

\*Due to technical limitations the following pesticides could not be analysed: Dithiocarbamates (expressed as CS<sub>2</sub>), Methoxychlor and Tetradifon.

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 July 2020

Dr. M.J. van de Velde

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