



## 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: **20B17EY20D08**  
Order numbers: containers: 369291 to 369302  
bags: not available  
Grower/drier: Bedrocan BV      harvest date/period:  
P.O. Box 2009      17 February 2020  
NL- 9640 CA Veendam  
Gamma irradiation: Synergy Health      date:      dose:  
Soeverinstraat 2      8 April 2020      ≥ 10,0 kGy  
NL-4879 NN Etten-Leur  
Packager: Fagron BV      date:  
Venkelbaan 101      14 – 26 May 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 BV  
Heembadweg 5      Middenkampweg 17  
NL-9561 CZ Ter Apel      NL-6545 CH Nijmegen  
Analysis number: 1. 23339      2. AAH93707  
Report date: 1. 23 June 2020      2. 27 May 2020  
Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014

|                                  | <b>Method</b> | <b>Specification</b>   | <b>Result</b> |
|----------------------------------|---------------|--|---------------|
| Appearance                       | monograph     | brown green clustered<br>flowers of 1,5 to 3 cm with a<br>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<br>vermin are absent   | conform       |
| Fineness                         | monograph     | • no leaves shooting out<br>more than 20% of the<br>length of the flowers<br>• stalks are cut away<br>directly under the bottom<br>flowers of the<br>inflorescence | conform       |



|  | Method  | Specification                 | Result           |
|--|---|-------------------------------|------------------|
| Microbiological purity   | Ph. Eur (current ed.)<br>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.)<br>"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) | $\leq 4$ $\mu$ g/kg           | < 4.0 $\mu$ g/kg |
| Absence of pesticides  | Ph. Eur (current ed.)<br>"Pesticide residues" (2.8.13)  | $\leq$ Limits Ph. Eur 2.8.13* | conform          |
| Absence of heavy metal   | Ph. Eur (current ed.)   |                               |                  |
| <i>lead</i>  | "Heavy metals in herbal drugs and fatty oils" (monograph)   | max. 20.0 ppm                 | < 5 ppm          |
| <i>mercury</i>   |   | max. 0.5 ppm                  | < 0.125 ppm      |
| <i>cadmium</i>   |   | max. 0.5 ppm                  | < 0.125 ppm      |
| Loss on drying   | Ph. Eur (current ed.)<br>"Loss on drying" meth. C (2.2.32)  | $\leq 10.0$ %                 | 8.3 %            |
| Assay (HPLC)   |   |                               |                  |
| <i>tetrahydrocannabinol(THC)</i>                                   | monograph   | approx. 22 %                  | 22.3 %           |
| <i>cannabidiol (CBD)</i>   | monograph   | < 1.0 %                       | < 0.1 %          |
| Related substances (HPLC)  |   |                               |                  |
| <i>cannabinol (CBN)</i>  | monograph   | < 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, 30 June 2020

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