



## Release certificate

|                           |   |  |                     |
|---------------------------|---|--|---------------------|
| <b>Product:</b>           | <b>Cannabis flos, variety Bedrocan (hemp flowers)</b>               |  |                     |
| <b>Country:</b>           | to be sold on the pharmaceutical market                             |  |                     |
| <b>Strength:</b>          | dronabinol: approx. 22%   | cannabidiol : <1.0%                                      |                     |
| <b>Dosage form:</b>       | flowers   |  |                     |
| <b>Package size:</b>      | 5 grams in container  |  |                     |
| <b>Batch:</b>             | <b>17111EY18F27</b>   |  |                     |
| <b>Order numbers:</b>     | 349865 to 349874  |  |                     |
| <b>Grower/drier:</b>      | Bedrocan BV<br>P.O. Box 2009<br>NL- 9640 CA Veendam                 | harvest date/period:<br>11 September 2017                |                     |
| <b>Gamma irradiation:</b> | Synergy Health<br>Soevereinstraat 2<br>NL-4879 NN Etten-Leur        | date:<br>27 June 2018                                    | dose:<br>≥ 10,0 kGy |
| <b>Packager:</b>          | Fagron BV<br>Venkelbaan 101<br>NL-2908 KE Capelle a/d IJssel        | date:<br>5 – 16 July 2018                                |                     |
| <b>Part of analysis:</b>  | 1.general analysis  | 2.microbiology of end product in container               |                     |
| <b>Laboratories:</b>      | 1. PROXY Laboratories BV<br>Archimedesweg 25<br>NL-2333 CM Leiden   | 2. Bactimm BV<br>Middenkampweg 17<br>NL-6545 CH Nijmegen |                     |
| <b>Analysis number:</b>   | 1. 394-0102814  | 2. 08.620  |                     |
| <b>Report date:</b>       | 1. 24 oktober 2017  | 2. 24 July 2018  |                     |
| <b>Testing method:</b>    | Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014 |  |                     |
| <b>End check:</b>         | Office of Medicinal Cannabis  | date: 20 July 2018                                       |                     |

|                                  | <b>Method</b> | <b>Specification</b>  | <b>Result</b> |
|----------------------------------|---------------|---|---------------|
| 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 chromatography</i> | monograph     | monograph   | conform       |
| Foreign material                 | monograph     | stalks, insects and other vermin are absent   | conform       |
| Fineness                         | monograph     | <ul style="list-style-type: none"> <li>• no leaves shooting out more then 20% of the length of the flowers</li> <li>• stalks are cut away directly under the bottom flowers of the inflorescence</li> </ul> | 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.  | ≤10 <sup>2</sup> 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.)<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) | < 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                | 0.3 ppm       |
| <i>mercury</i>   | "Heavy metals in   | max. 0.5 ppm                 | < 0.1 ppm     |
| <i>cadmium</i>   | herbal drugs and fatty oils" (monograph)   | max. 0.5 ppm                 | < 0.1 ppm     |
| Loss on drying   | Ph. Eur (current ed.)<br>"Loss on drying" meth. C (2.2.32)   | ≤10.0 %                      | 10.0 %        |
| Assay (UPLC)   |  |                              |               |
| <i>fingerprint</i>   | monograph  | similar                      | conform       |
| <i>dronabinol (THC)</i>  | monograph  | approx. 22 %                 | 22.5 %        |
| <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               | ± 5.11 gram   |
| Expiry date  |  |                              | 06 / 2019     |

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, 26 July 2018

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

Dr. M.J. van de Velde