



Release certificate

| | | |
|---------------------------|---|--|
| Product: | Cannabis flos, variety Bedrocan (hemp flowers) | |
| Country: | to be sold on the pharmaceutical market | |
| Strength: | dronabinol: approx. 22% | cannabidiol : <1.0% |
| Dosage form: | flowers | |
| Package size: | 5 grams in container | |
| Batch: | 15J26EY16C08 | |
| Order numbers: | containers: 317894 to 317905 | |
| Grower/drier: | Bedrocan BV P.O. Box 2009 NL- 9640 CA Veendam | harvest date/period: 26 October 2015 |
| Gamma irradiation: | Synergy Health Soeverinstraat 2 NL-4879 NN Etten-Leur | date: 24 November 2015 dose: $\geq 10,0$ kGy |
| Packager: | Fagron BV Venkelbaan 101 NL-2908 KE Capelle a/d IJssel | date: 28 April -11 May 2016 |
| Part of analysis: | 1.general analysis | 2.microbiology of end product in container |
| Laboratories: | 1. PROXY Laboratories BV Archimedesweg 25 NL-2333 CM Leiden | 2. Bactimm BV Middenkampweg 17 NL-6545 CH Nijmegen |
| Analysis number: | 1. 394-0087168 | 2. 07.161 |
| Report date: | 1. 18 December 2015 | 2. 17 May 2016 |
| Testing method: | Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014 | |
| End check: | Office of Medicinal Cannabis | date: 18 May 2016 |

| | 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 then 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. | ≤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 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 % | 10 % |
| Assay (UPLC) | | | |
| <i>fingerprint</i> | monograph | similar | conform |
| <i>dronabinol (THC)</i> | monograph | approx. 22 % | 23.9 % |
| <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 | ±5.04 gram |
| Expiry date | | | 11/ 2016 |

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, 20 May 2016

Dr. M.J. van de Velde

head, Office of Medicinal Cannabis