



Release certificate

Product: Cannabis flos, variety **Bedrolite (hemp flowers), granulated**
Country: to be sold on the pharmaceutical market
Strength: tetrahydrocannabinol: < 1.0% cannabidiol: approx. 9%
Dosage form: flowers
Package size: 5 grams in container, 400 grams in bags
Batch: **19L02FR20B19**
Order numbers: containers: 368010 and 368011
bags: 368009
Grower/drier: Bedrocan BV harvest date/period:
P.O. Box 2009 2 December 2019
NL- 9640 CA Veendam
Gamma irradiation: Synergy Health date: dose:
Soeverinstraat 2 19 February 2020 ≥ 10,0 kGy
NL-4879 NN Etten-Leur
Packager: Fagron BV date:
Venkelbaan 101 30 – 31 March 2020
NL-2908 KE Capelle a/d IJssel
Part of analysis: 1.general analysis 2.microbiology of end product in
container
Laboratories: 1. PROXY Laboratories BV 2. Bactimm BV
Archimedesweg 25 Middenkampweg 17
NL-2333 CM Leiden NL-6545 CH Nijmegen
Analysis number: 1. 394-0118154 2. AAH24382
Report date: 1. 21 March 2020 2. 14 April 2020
Testing method: Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014
End check: Office of Medicinal Cannabis date: 6 April 2020

| | 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 1,0 – 1,5 cm | 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 metals | | | |
| <i>lead</i> | Ph. Eur (current ed.) | max. 20.0 ppm | 1.07 ppm |
| <i>mercury</i> | "Heavy metals in herbal drugs and fatty oils" (monograph) | max. 0.5 ppm | < 0.05 ppm |
| <i>cadmium</i> | | max. 0.5 ppm | 0.08 ppm |
| Loss on drying | Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32) | ≤10.0 % | 8.9 % |
| Assay (UPLC) | | | |
| <i>fingerprint</i> | monograph | similar | conform |
| <i>tetrahydrocannabinol(THC)</i> | monograph | < 1.0 % | 0.3 % |
| <i>cannabidiol (CBD)</i> | monograph | approx. 9 % | 8.0 % |
| 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 | | | 02 / 2021 |

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, 15 April 2020


Dr. M.J. van de Velde

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head, Office of Medicinal Cannabis