



Release certificate

| | | | |
|--------------------|---|--|-------------------------------------|
| Product: | Cannabis flos, variety Bedrocan (hemp flowers) | | |
| Country: | to be sold on the pharmaceutical market | | |
| Strength: | tetrahydrocannabinol: ca. 22% | cannabidiol: < 1.0% | |
| Dosage form: | flowers | | |
| Package size: | 5 grams in container, 400 grams in bags | | |
| Batch: | 22H08EY22J26 | | |
| Order numbers: | containers: 383431 to 383442 bags: 383444 | | |
| Grower/drier: | Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam | harvest date/period: | 08 August 2022 |
| Gamma irradiation: | Synergy Health Ede B.V. Soevereinstraat 2 NL-4879 NN Etten-Leur | date: | 26 October 2022 |
| | | dose: | ≥ 10,0 kGy |
| Packager: | Fagron B.V. Venkelbaan 101 NL-2908 KE Capelle a/d IJssel | date: | 29 November 2022 – 12 December 2022 |
| Laboratory: | Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel | 1. General analysis Analysis number: 38988 Report date: 20 September 2022 | |
| | | 2. Microbiology of end product in container Analysis number: 40978 Report date: 16 December 2022 | |
| Testing method: | OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021 | | |

| | Method | Specification | Result |
|---|--|---|---------------|
| Characters | Monograph | Odour characteristic for Cannabis flower. Leaves shoot out no more than 20% of the length of the flower and stalks are mostly cut off directly under the bottom site of the flowers | conform |
| Identification | | | |
| <i>Macroscopic botanical characters</i> | Visual | Brown, green clustered flowers of about 1.5 to 3.0 cm length | conform |
| <i>Microscopic botanical characters</i> | Monograph | Gland hairs are mainly observed | conform |
| <i>Thin-layer chromatography</i> | Ph. Eur. (current ed.) 2.2.27, Monograph | Comparable with reference | conform |



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Our reference

22H08EY22J26

| | | | |
|--|----------------------------------|------------------------------------|-------------------|
| Foreign material | Visual | Free from insects and other vermin | conform |
| Microbial contamination | Ph. Eur. (current ed.) | | |
| <i>Total aerobic microbial count (TAMC)</i> | 2.6.12, 2.6.13 | $\leq 10^2$ cfu/gram | $< 10^2$ cfu/gram |
| <i>Total combined yeasts/moulds count (TYMC)</i> | | $\leq 10^1$ cfu/gram | $< 10^1$ cfu/gram |
| <i>S. aureus, P. aeruginosa, bile-tolerant gram-negative bacteria</i> | | Absent (1 gram) | conform |
| Aflatoxins | Monograph | | |
| <i>Aflatoxin B₁</i> | | ≤ 2 µg/kg | < 2.0 µg/kg |
| <i>Sum of aflatoxins B₁, B₂, G₁ and G₂</i> | | ≤ 4 µg/kg | < 4.0 µg/kg |
| Pesticides | Ph. Eur. (current ed.) 2.8.13 | \leq Limits Ph. Eur. 2.8.13* | conform |
| Heavy metals | Ph. Eur. (current ed.) | | |
| <i>Lead</i> | 2.4.27, 2.2.58 | max. 20.0 ppm | < 5 ppm |
| <i>Cadmium</i> | | max. 0.5 ppm | < 0.125 ppm |
| <i>Mercury</i> | | max. 0.5 ppm | < 0.125 ppm |
| Loss on drying | Ph. Eur. (current ed.) 2.2.32 | ≤ 10.0 % | 8.8 % |
| Assay (HPLC) | Ph. Eur. (current ed.) | | |
| <i>Tetrahydrocannabinol (THC, total equivalent)</i> | 2.2.29, Monograph | 22 % [17.6 – 26.4] | 20.8 % |
| <i>Cannabidiol (CBD, total equivalent)</i> | | < 1.0 % | 0.1 % |
| Related substances (HPLC) | Ph. Eur. (current ed.) | | |
| <i>Cannabinol (CBN, total equivalent)</i> | 2.2.29, Monograph | ≤ 1.0 % | < 0.1 % |
| Content of container | BMC-SWV 360 | 5 gram | ± 5.15 gram |
| Expiry date | | | Oct. 2023 |

*The following pesticides are not analysed: dithiocarbamates (expressed as CS₂), methoxychlor, paraoxon-methyl and tetradifon. The limit of detection is increased for fenpropathrin to 0.1 mg/kg and azinphos-ethyl to 1 mg/kg.

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, 22 December 2022

Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis

Dr. M.J. van de Velde