Ministry of Health, Welfare and Sport

**Office of Medicinal Cannabis**

# Release certificate

| | | | |
|---|---|---|---|
| Product: | **Cannabis flos, variety Bedrolite (hemp flowers), granulated** | | |
| Country: | to be sold on the pharmaceutical market | | |
| Strength: | tetrahydrocannabinol: < 1.0% | cannabidiol: ca. 7.5% | |
| Dosage form: | flowers | | |
| Package size: | 5 grams in container, 400 grams in bags | | |
| Batch: | **24L09FR25A15** | | |
| Order numbers: | containers: 386997<br>bags: 386998 | | |
| Grower/drier: | Bedrocan Nederland B.V.<br>P.O. Box 2009<br>NL- 9640 CA Veendam | harvest date/period:<br>09 Dec. 2024 | |
| Gamma irradiation: | Synergy Health Ede B.V.<br>Soevereinstraat 2<br>NL-4879 NN Etten-Leur | date:<br>15 Jan. 2025 | dose:<br>≥ 10,0 kGy |
| Packager: | Fagron Nederland B.V.<br>Venkelbaan 101<br>NL-2908 KE Capelle a/d IJssel | date:<br>5-6 Feb. 2025 | |
| Laboratory: | Laboratorium Ofichem B.V.<br>Heembadweg 5<br>NL-9561 CZ Ter Apel | 1. General analysis<br>Analysis number: 51824<br>Report date: 21 Jan. 2025<br>2. Microbiology of end product in container<br>Analysis number: 52365<br>Report date: 18 Feb 2025 | |
| Testing method: | OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021 | | |

| | **Method** | **Specification** | **Result** |
|---|---|---|---|
| Characters | Monograph | Odour characteristic for Cannabis flower. Does not contain stalks that are longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm | Conform |
| Identification | | | Conform |
| *Macroscopic botanical characters* | Visual | Brown, green granulates of flowers of about 4 to 6 mm in diameter | |
| *Microscopic botanical characters* | Monograph | Gland hairs are mainly observed | Conform |
| *Thin-layer chromatography* | Ph. Eur. (current ed.) 2.2.27, Monograph | Comparable with reference | Conform |
| Foreign material | Visual | Free from insects and other vermin | Conform |

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| | | | |
|---|---|---|---|
| Microbial contamination | Ph. Eur. (current ed.) | | |
| *Total aerobic microbial count (TAMC)* | 2.6.12, 2.6.13 | ≤$10^2$ cfu/gram | < $10^2$ cfu/gram |
| *Total combined yeasts/moulds count (TYMC)* | | ≤$10^1$ cfu/gram | < $10^1$ cfu/gram |
| *S. aureus, P. aeruginosa, bile-tolerant gram-negative bacteria* | | Absent (1 gram) | Conform |
| Aflatoxins | Monograph | | |
| *Aflatoxin $B_1$* | | ≤ 2 µg/kg | < 2.0 µg/kg |
| *Sum of aflatoxins $B_1$, $B_2$, $G_1$ and $G_2$* | | ≤ 4 µg/kg | < 4.0 µg/kg |
| Pesticides | Ph. Eur. (current ed.) 2.8.13 | ≤ Limits Ph. Eur. 2.8.13* | Conform |
| Heavy metals | Ph. Eur. (current ed.) | | |
| *Lead* | 2.4.27, 2.2.58 | max. 20.0 ppm | < 5 ppm |
| *Cadmium* | | max. 0.5 ppm | < 0.125 ppm |
| *Mercury* | | max. 0.5 ppm | < 0.125 ppm |
| Loss on drying | Ph. Eur. (current ed.) 2.2.32 | ≤ 10.0 % | 7.7 % |
| Assay (HPLC) | Ph. Eur. (current ed.) | | |
| *Tetrahydrocannabinol (THC, total equivalent)* | 2.2.29, Monograph | < 1.0 % | 0.3 % |
| *Cannabidiol (CBD, total equivalent)* | | 7.5 % [6.0 – 9.0] | 8.5 % |
| Related substances (HPLC) | Ph. Eur. (current ed.) | | |
| *Cannabinol (CBN, total equivalent)* | 2.2.29, Monograph | ≤ 1.0 % | < 0.1 % |
| Content of container | BMC-SWV 455 | 5 gram | ± 5.15 gram |
| Expiry date | | | 30 Nov. 2025 |

**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, 20 February 2025

S. Vos- de Schipper / M. Mennens
QA, Office of Medicinal Cannabis