



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: **24G29FR24104**
Order numbers: containers: 386739
bags: 386740
Grower/drier: Bedrocan Nederland B.V. harvest date/period:
P.O. Box 2009 29 Jul 2024
NL- 9640 CA Veendam
Gamma Synergy Health Ede B.V. date: dose:
irradiation: Soevereinstraat 2 04 Sep 2024 ≥ 10,0 kGy
NL-4879 NN Etten-Leur
Packager: Fagron Nederland B.V. date:
Venkelbaan 101 23 Oct 2024
NL-2908 KE Capelle a/d IJssel
Laboratory: Laboratorium Ofichem B.V. 1. General analysis
Heembadweg 5 Analysis number: 50251
NL-9561 CZ Ter Apel Report date: 03 Sep 2024
2. Microbiology of end product in container
Analysis number: 51169
Report date: 06 Nov 2024
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 | | | |
| <i>Macroscopic botanical characters</i> | Visual | Brown, green granulates of flowers of about 4 to 6 mm in diameter | 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 |
| Foreign material | Visual | Free from insects and other vermin | conform |



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Our reference

24G29FR24I04

| | | | |
|--|----------------------------------|----------------------------|----------------------------|
| Microbial contamination | Ph. Eur. (current ed.) | | |
| <i>Total aerobic microbial count (TAMC)</i> | 2.6.12, 2.6.13 | ≤ 10 ² cfu/gram | < 10 ² cfu/gram |
| <i>Total combined yeasts/moulds count (TYMC)</i> | | ≤ 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 | ≤ 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 % | 9.2 % |
| Assay (HPLC) | Ph. Eur. (current ed.) | | |
| <i>Tetrahydrocannabinol (THC, total equivalent)</i> | 2.2.29, Monograph | < 1.0 % | 0.3 % |
| <i>Cannabidiol (CBD, total equivalent)</i> | | 7.5 % [6.0 – 9.0] | 7.8 % |
| 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 455 | 5 gram | ± 5.13 gram |
| Expiry date | | | 30 Jun 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, 07 Nov 2024

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