



Specification Sheet

(Valid until implementation of EP Monograph 7/2024:3028 Cannabis flower, according to CC2024-003)

Product: **Cannabis flos, variety Bedrolite** (hemp flowers)
Market: to be sold on the pharmaceutical market
Strength: tetrahydrocannabinol: $\leq 1.0\%$ cannabidiol: ca. 7.5%
Dosage form: flowers, granulated
Package size: 5 grams in containers, 400 grams in bags
Analytical Monograph: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

| | Method | Specification | |
|-----------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------------|--------------------------------|
| Odour | Ph. Eur. (current ed.) 2.3.4 | Characteristic for Cannabis flower | |
| Appearance | Visual | Stalks are no longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm | |
| Identification | | | |
| <i>Macroscopic botanical characters</i> | Visual | Brown, green granulates of flowers of about 4 to 6 mm in diameter | |
| <i>Microscopic botanical characters</i> | Monograph | Gland hairs are mainly observed | |
| <i>Thin-layer chromatography</i> | Ph. Eur. (current ed.) 2.2.27, Monograph | Comparable with reference | |
| Loss on drying | Ph. Eur. (current ed.) 2.2.32 | $\leq 10.0\%$ | |
| Foreign material | Visual | Free from insects and other vermin | |
| Aflatoxins | Monograph | Aflatoxin B1 | $\leq 2 \mu\text{g}/\text{kg}$ |
| | | Sum of aflatoxins B1, B2, G1 and G2 | $\leq 4 \mu\text{g}/\text{kg}$ |
| Pesticides | Ph. Eur. (current ed.) 2.8.13 | \leq Limits Ph. Eur. 2.8.13 | |

Office of Medicinal Cannabis
P.O. Box 16114
NL-2500 BC THE HAGUE
The Netherlands
Telephone +31 70 340 5113

Address:
Hoftoren
Rijnstraat 50
NL-2515 XP THE HAGUE
The Netherlands

The Office of Medicinal Cannabis (OMC) is part of the CIBG agency of the Ministry of Health, Welfare and Sport

Internet address:
www.minvws.nl
www.cannabisbureau.nl
e-mail:
info@cannabisbureau.nl



| | Method | Specification | |
|-------------------------|---------------------------------------------|-------------------------------------------|----------------------------|
| Heavy metals | Ph. Eur. (current ed.) 2.4.27, 2.2.58 | Lead | ≤ 20.0 ppm |
| | | Cadmium | ≤ 0.5 ppm |
| | | Mercury | ≤ 0.5 ppm |
| Assay | Ph. Eur. (current ed.) 2.2.29, Monograph | Tetrahydrocannabinol (THC, total eq.) | ≤ 1.0% |
| | | Cannabidiol (CBD, total eq.) | 7.5% [6.0 – 9.0] |
| Related substances | Ph. Eur. (current ed.) 2.2.29, Monograph | Cannabinol (CBN, total eq.) | ≤ 1.0% |
| Microbial contamination | Ph. Eur. (current ed.) 2.6.12, 2.6.13 | Total aerobic microbial count (TAMC) | ≤ 10 ² CFU/gram |
| | | Total combined yeasts/moulds count (TYMC) | ≤ 10 ¹ CFU/gram |
| | | <i>Staphylococcus aureus</i> | Absent (1 gram) |
| | | <i>Pseudomonas aeruginosa</i> | Absent (1 gram) |
| | | Bile-tolerant gram-negative bacteria | Absent (1 gram) |