

## 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

bags:

Package size:

5 grams in container, 400 grams in bags

Batch:

24H26EY24I25

Order numbers:

containers: 386795

Grower/drier:

386834

Bedrocan Nederland B.V.

harvest date/period: 26 Aug. 2024

25 Sep. 2024

P.O. Box 2009

Gamma

NL-9640 CA Veendam

dose:

irradiation:

Synergy Health Ede B.V.

date:

≥ 10,0 kGy

Soevereinstraat 2 NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101 01 Nov. 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 50461 Report date: 24 Sep. 2024

Microbiology of end product in container

Analysis number: 51257 Report date: 13 Nov. 2024

Testing method:

OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

|                           | Method                 | Specification            | Result  |
|---------------------------|------------------------|--------------------------|---------|
| Characters                | Monograph              | Odour characteristic for | Conform |
|                           |                        | 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              |         |
| Identification            |                        |                          | Conform |
| Macroscopic botanical     | Visual                 | Brown, green clustered   |         |
| characters                |                        | flowers of about 1.5 to  |         |
|                           |                        | 3.0 cm length            |         |
| Microscopic botanical     | Monograph              | Gland hairs are mainly   | Conform |
| characters                |                        | observed                 |         |
| Thin-layer chromatography | Ph. Eur. (current ed.) | Comparable with          | Conform |
|                           | 2.2.27, Monograph      | reference                |         |

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 24H26EY24I25

| 241120L 1 24125                                                       |                                  |                                    |           |                   |              |
|-----------------------------------------------------------------------|----------------------------------|------------------------------------|-----------|-------------------|--------------|
| Foreign material                                                      | Visual                           | Free from insects and other vermin |           | Conform           |              |
| Microbial contamination                                               | Ph. Eur. (current ed.)           |                                    |           |                   |              |
| Total aerobic microbial count (TAMC)                                  | ,                                |                                    | m         | < 10²             | cfu/gram     |
| Total combined<br>yeasts/moulds count<br>(TYMC)                       |                                  | ≤10¹ cfu/gram                      |           | < 10¹             | cfu/gram     |
| S. aureus, P. aeruginosa,<br>bile-tolerant gram-<br>negative bacteria |                                  | Absent (1 gra                      | m)        | Conf              | orm          |
| Aflatoxins                                                            | Monograph                        |                                    |           |                   |              |
| Aflatoxin B₁                                                          |                                  | ≤ 2 µg/kg                          |           | < 2.0             | μg/kg        |
| Sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> ,                   |                                  | ≤ 4 µg/kg                          |           |                   | μg/kg        |
| G₁ and G₂                                                             |                                  | , , ,                              |           |                   |              |
| Pesticides                                                            | Ph. Eur. (current ed.)<br>2.8.13 | ≤ Limits Ph. Eur. 2                | 2.8.13*   | Conf              | orm          |
| 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.)<br>2.2.32 | ≤ 10.0                             | %         | 8.9               | %            |
| Assay (HPLC)                                                          | Ph. Eur. (current ed.)           |                                    |           |                   |              |
| Tetrahydrocannabinol<br>(THC, total equivalent)                       | 2.2.29, Monograph                | 22 % [17.6                         | 6 – 26.4] | 20.8              | %            |
| Cannabidiol (CBD, total equivalent)                                   |                                  | <1.0                               | %         | 0.2               | %            |
| Related substances (HPLC)                                             | Ph. Eur. (current ed.)           |                                    |           |                   |              |
| Cannabinol (CBN, total equivalent)                                    | 2.2.29, Monograph                | ≤ 1.0                              | %         | < 0.1             | %            |
| Content of container<br>Expiry date                                   | BMC-SWV 455                      | 5                                  | gram      | ± 5.15<br>31 Jul. | gram<br>2025 |
|                                                                       |                                  |                                    |           |                   |              |

<sup>\*</sup>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, 18 November 2024

K. Amponsah / M. Mennens

QA, Office of Medicinal Cannabis