

## Office of Medicinal Cannabis



## 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:

24K04EY24K27

Order numbers:

containers: 386945 to 386951

bags:

386952

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

Gamma

NL- 9640 CA Veendam

date:

dose:

irradiation:

Synergy Health Ede B.V. Soevereinstraat 2

27 Nov 2024

04 Nov 2024

≥ 10,0 kGy

Daniela

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

Velikeibaali 101

14 – 24 Jan 2025

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

Mathad

NL-9561 CZ Ter Apel

1. General analysis

Analysis number: 51285 Report date: 03 Dec 2024

2. Microbiology of end product in container

Analysis number: 52131 Report date: 28 Jan 2025

Testing method:

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

Consideration

|                                  | 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                   |                        |                                 |         |  |
| Macroscopic botanical            | Visual                 | Brown, green clustered          |         |  |
| characters                       |                        | flowers of about 1.5 to         | conform |  |
|                                  |                        | 3.0 cm length                   |         |  |
| Microscopic botanical characters | Monograph              | Gland hairs are mainly observed | conform |  |
| Thin-layer chromatography        | Ph. Eur. (current ed.) | Comparable with                 | conform |  |
|                                  | 2.2.27, Monograph      | reference                       |         |  |
|                                  |                        |                                 |         |  |

## Ministry of Health, Welfare and Sport

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Page 2

Our reference

24K04EY24K27

| 24KU4E Y 24K27  |                                  |                                    |           |                  |          |
|---|----------------------------------|------------------------------------|-----------|------------------|----------|
| Foreign material  | Visual                           | Free from insects and other vermin |           | conform          |          |
| Microbial contamination   | Ph. Eur. (current ed.)           |                                    |           |                  |          |
| Total aerobic microbial count (TAMC)                                  | 2.6.12, 2.6.13                   | ≤10² cfu/gram                      |           | < 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 gram)                    |           | conform          |          |
| Aflatoxins  | Monograph                        |                                    |           |                  |          |
| Aflatoxin B <sub>1</sub>  |                                  | ≤ 2 µg/kg                          |           | < 2.0            | µg/kg    |
| Sum of aflatoxins B <sub>1</sub> , B <sub>2</sub> ,                   |                                  | ≤ 4 µg/kg                          |           | < 4.0            | µg/kg    |
| $G_1$ and $G_2$   |                                  |                                    |           |                  |          |
| Pesticides  | Ph. Eur. (current ed.)<br>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.)<br>2.2.32 | ≤ 10.0                             | %         | 8.2              | %        |
| Assay (HPLC)  | Ph. Eur. (current ed.)           |                                    |           |                  |          |
| Tetrahydrocannabinol<br>(THC, total equivalent)                       | 2.2.29, Monograph                | 22 % [17.6                         | 6 – 26.4] | 20.5             | %        |
| 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 Oct |          |

<sup>\*</sup>The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl 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, 30 January 2025

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