

## Release certificate

Product:

Cannabis flos, variety Bedica (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 14%

cannabidiol: < 1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

23A30FP23D12

Order numbers:

containers: 384554 to 384555

bags:

384557

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

30 Jan. 2023

12 Apr. 2023

P.O. Box 2009

Gamma

NL-9640 CA Veendam

date:

dose:

irradiation:

Synergy Health Ede B.V.

≥ 10,0 kGy

Soevereinstraat 2

NL-4879 NN Etten-Leur

Packager: Fagron B.V.

Venkelbaan 101

03 May 2023 - 09 May 2023

NL-2908 KE Capelle a/d IJssel Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis

Analysis number: 42119

Report date: 06 March 2023

Microbiology of end product in container

Analysis number: 43805 Report date: 22 May 2023

Testing method:

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

| Characters                       | <b>Method</b><br>Monograph                  | Specification 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 | <b>Result</b><br>conform |
|----------------------------------|---|---|--------------------------|
| Identification                   |   |   |                          |
| Macroscopic botanical characters | Visual                                      | Brown, green granulates<br>of flowers of about 4 to 6<br>mm in diameter   | conform                  |
| Microscopic botanical characters | Monograph                                   | Gland hairs are mainly observed   | conform                  |
| Thin-layer chromatography        | Ph. Eur. (current ed.)<br>2.2.27, Monograph | Comparable with reference   | conform                  |
| Foreign material                 | Visual                                      | Free from insects and other vermin  | conform                  |
|                                  |   |   |                          |

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## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference

| 23A30FP23D12                                    |                                  |                     |           |                   |          |
|---|----------------------------------|---------------------|-----------|-------------------|----------|
| Microbial contamination                         | Ph. Eur. (current ed.)           |                     |           |                   |          |
| Total aerobic microbial                         | 2.6.12, 2.6.13                   | ≤10² cfu/gra        | m         | < 10 <sup>2</sup> | cfu/gram |
| count (TAMC)                                    |                                  |                     |           |                   |          |
| Total combined                                  |                                  | ≤10¹ cfu/gra        | m         | < 10 <sup>1</sup> | cfu/gram |
| yeasts/moulds count<br>(TYMC)                   |                                  |                     |           |                   |          |
| S. aureus, P. aeruginosa,                       |                                  |                     |           |                   |          |
| bile-tolerant gram-                             |                                  | Absent (1 gram)     |           | conform           |          |
| negative bacteria                               |                                  |                     |           |                   |          |
| Aflatoxins                                      | Monograph                        |                     |           |                   |          |
| Aflatoxin B₁                                    |                                  | ≤ 2 µg/kg           |           |                   | µg/kg    |
| Sum of aflatoxins $B_1$ , $B_2$ ,               |                                  | ≤ 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 | 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              | %         | 7.4               | %        |
| Assay (HPLC)                                    | Ph. Eur. (current ed.)           |                     |           |                   |          |
| Tetrahydrocannabinol<br>(THC, total equivalent) | 2.2.29, Monograph                | 14 % [11.2          | 2 – 16.8] | 15.2              | %        |
| Cannabidiol (CBD, total equivalent)             |                                  | <1.0                | %         | 0.1               | %        |
| Related substances (HPLC)                       | Ph. Eur. (current ed.)           |                     |           |                   |          |
| Cannabinol (CBN, total equivalent)              | 2.2.29, Monograph                | ≤ 1.0               | %         | < 1.0             | %        |
| Content of container                            | BMC-SWV 360                      | 5                   | gram      | ± 5.14            | gram     |
| Expiry date                                     |                                  |                     |           | 30 Apr.           | 2024     |

<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, 25 May 2023

K. Amponsah / R.V. Goormachtigh

QA, Office of Medicinal Cannabis