

Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

## Release certificate

Product: Cannabis flos, variety Bedrocan (hemp flowers)

to be sold on the pharmaceutical market Country:

tetrahydrocannabinol: ca. 22% cannabidiol: < 1.0% Strength:

Dosage form: flowers

Package size: 5 grams in container, 400 grams in bags

Batch: 22L05EY23C22

Order numbers: containers: 384382 to 384388

> 384390 bags:

Grower/drier: Bedrocan Nederland B.V.

harvest date/period: P.O. Box 2009 05 December 2022

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. dose: date: irradiation: Soevereinstraat 2 22 March 2023 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron B.V. date:

> Venkelbaan 101 13 April 2023 - 24 April 2023

NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V.

1. General analysis Heembadweg 5 Analysis number: 41222 NL-9561 CZ Ter Apel Report date: 19 January 2023

Microbiology of end product in container

Analysis number: 43640 Report date: 09 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. 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 | <b>Result</b><br>conform |
|---------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Identification  Macroscopia botanical | Visual                                      | Prown groon alustared                                                                                                                                                                             |                          |
| Macroscopic botanical characters      | Visual                                      | Brown, green clustered flowers of about 1.5 to 3.0 cm length                                                                                                                                      | 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                  |

The Netherlands

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| 22L05EY23C22                                      |                                  |                                       |           |                  |          |
|---------------------------------------------------|----------------------------------|---------------------------------------|-----------|------------------|----------|
| Foreign material                                  | Visual                           | Free from insection other vermination |           | conf             | orm      |
| Microbial contamination                           | Ph. Eur. (current ed.)           |                                       |           |                  |          |
| Total aerobic microbial count (TAMC)              | 2.6.12, 2.6.13                   | ≤10² cfu/gra                          | m         | ≤10 <sup>2</sup> | cfu/gram |
| Total combined<br>yeasts/moulds count<br>(TYMC)   |                                  | ≤10¹ cfu/gra                          | m         | ≤10¹             | cfu/gram |
| S. aureus, P. aeruginosa,                         |                                  |                                       |           |                  |          |
| bile-tolerant gram-<br>negative bacteria          |                                  | Absent (1 gra                         | am)       | conf             | orm      |
| Aflatoxins                                        | Monograph                        |                                       |           |                  |          |
| Aflatoxin B <sub>1</sub>                          |                                  | ≤ 2 µg/kg                             |           | < 2.0            | μg/kg    |
| Sum of aflatoxins $B_1$ , $B_2$ , $G_1$ and $G_2$ |                                  | ≤ 4 µg/kg                             |           | < 4.0            | µg/kg    |
| Pesticides                                        | Ph. Eur. (current ed.)<br>2.8.13 | ≤ Limits Ph. Eur.                     | 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                                | %         | 7.3              | %        |
| Assay (HPLC)                                      | Ph. Eur. (current ed.)           |                                       |           |                  |          |
| Tetrahydrocannabinol<br>(THC, total equivalent)   | 2.2.29, Monograph                | 22 % [17.6                            | 6 – 26.4] | 19.9             | %        |
| 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                                 | %         | < 0.1            | %        |
| Content of container                              | BMC-SWV 360                      | 5                                     | gram      | ± 5.15           | gram     |
| Expiry date                                       |                                  |                                       |           | 31 March         | 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

K. Amponsah / S. Vos- de Schipper

QA, Office of Medicinal Cannabis