

## 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:

24I16EY24J09

Order numbers:

containers: 386840 386842

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

16 Sep 2024

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

Venkelbaan 101

09 Oct 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

12 Nov 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel 1. General analysis

> Analysis number: 50753 Report date: 14 Oct 2024

Microbiology of end product in container

Analysis number: 51352 Report date: 20 Nov 2024

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 | Result<br>conform |
|----------------------------------|---|---|-------------------|
| Identification                   | Viewel                                      | Description of the state of   |                   |
| 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           |

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The Netherlands

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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| 24I16EY24J09   |                                  |                                |         |                   |          |
|--|----------------------------------|--------------------------------|---------|-------------------|----------|
| Foreign material   | Visual                           | Free from insects other vermin |         |                   | orm      |
| Microbial contamination  | Ph. Eur. (current ed.)           |                                |         |                   |          |
| Total aerobic microbial count (TAMC)   | 2.6.12, 2.6.13                   | ≤10² cfu/gram                  |         | < 10 <sup>2</sup> | cfu/gram |
| Total combined<br>yeasts/moulds count<br>(TYMC)<br>S. aureus, P. aeruginosa, |                                  | ≤10¹ cfu/gram                  |         | < 10 <sup>1</sup> | cfu/gram |
| bile-tolerant gram-<br>negative bacteria                                     |                                  | Absent (1 gram                 | 1)      | 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          | 8.13*   | conf              | orm      |
| Heavy metals   | Ph. Eur. (current ed.)           |                                |         |                   |          |
| Lead   | 2.4.27, 2.2.58                   | max. 20.0 p                    | pm      | < 5               | ppm      |
| Cadmium  |                                  | max. 0.5 p                     | pm      | < 0.125           | ppm      |
| Mercury  |                                  | max. 0.5 p                     | pm      | < 0.125           | ppm      |
| Loss on drying   | Ph. Eur. (current ed.) 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 -                   | - 26.4] | 22.1              | %        |
| Cannabidiol (CBD, total equivalent)  |                                  | <1.0 %                         | %       | 0.3               | %        |
| Related substances (HPLC)  | Ph. Eur. (current ed.)           |                                |         |                   |          |
| Cannabinol (CBN, total equivalent)   | 2.2.29, Monograph                | ≤ 1.0 %                        | %       | < 0.1             | %        |
| Content of container Expiry date   | BMC-SWV 455                      | 5 g                            | gram    | ± 5.15            | 0        |
| man from V contracts   |                                  |                                |         | 0                 |          |

<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, 22 November 2024

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