

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: 22C07EY22F01

Order numbers: containers: 382209 to 382215

bags: 382216

Grower/drier: Bedrocan Nederland B.V. harvest date/period:

P.O. Box 2009 07 March 2022 NL- 9640 CA Veendam

Gamma Synergy Health Ede B.V. date:

irradiation: Soevereinstraat 2 01 June 2022  $\geq$  10,0 kGy NL-4879 NN Etten-Leur

Packager: Fagron B.V. date:

Venkelbaan 101 21 July 2022 – 01 August 2022

NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V. 1. General analysis

Heembadweg 5 Analysis number: 36092
NL-9561 CZ Ter Apel Report date: 26 April 2022

2. Microbiology of end product in container

Analysis number: 38473 Report date: 11 August 2022

dose:

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

Macroscopic botanical Visual Brown, green clustered

characters flowers of about 1.5 to conform

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

The Netherlands

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

Page

Our reference 22C07EY22F01

22C07EY22F01				
Foreign material	Visual	Free from insects and conform other vermin		
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 yeasts/moulds count (TYMC)		≤10¹ cfu/gram	<	10¹ cfu/gram
S. aureus, P. aeruginosa,				
bile-tolerant gram- negative bacteria		Absent (1 gram	) с	onform
Aflatoxins	Monograph			
Aflatoxin B <sub>1</sub>	• ,	≤ 2 µg/kg	<	2.0 µg/kg
Sum of aflatoxins $B_1$ , $B_2$ ,		≤ 4 µg/kg		4.0 μg/kg
$G_1$ and $G_2$		100		100
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8	3.13* c	onform
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 < 0.1	25 ppm
Mercury		max. 0.5 p	pm < 0.1	25 ppm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	ó	8.3 %
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 –	26.4] 2	1.3 %
Cannabidiol (CBD, total equivalent)		<1.0 %	ó	0.1 %
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 360	5 g		.14 gram lay 2023

<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.

Hague, the Netherlands, 15 August 2022

Head, Office of Madicion Carlos bis