

## Office of Medicinal Cannabis



## 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:

24F17FP24G10

Order numbers:

containers: 386441 to 386442

bags:

386443

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period: 17 June 2024

P.O. Box 2009

NL- 9640 CA Veendam

date:

dose:

Gamma irradiation:

Synergy Health Ede B.V.

10 July 2024

≥ 10,0 kGy

diation:

Soevereinstraat 2 NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

28 Aug. 2024 - 02 Sept. 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

1161

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. General analysis Analysis number: 49646

Heembadweg 5 NL-9561 CZ Ter Apel

Report date: 15 July 2024

Microbiology of end product in container

Analysis number: 50645 Report date: 24 Sept. 2024

Testing method:

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

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

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 24F17FP24G10			
Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram	< 10 <sup>2</sup> cfu/gram
count (TAMC)			
Total combined		≤10¹ cfu/gram	< 10 <sup>1</sup> cfu/gram
yeasts/moulds count			
(TYMC)			
S. aureus, P. aeruginosa,			
bile-tolerant gram-		Absent (1 gram)	Conform
negative bacteria			
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 $G_2$			
Pesticides	Ph. Eur. (current ed.) 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.)	≤ 10.0 %	8.4 %
	2.2.32		
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol	2.2.29, Monograph	14 % [11.2 – 16.8]	13.9 %
(THC, total equivalent)			
Cannabidiol (CBD, total		<1.0 %	0.1 %
equivalent)			
Related substances (HPLC)	Ph. Eur. (current ed.)		
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
equivalent)			
Content of container	BMC-SWV 455	5 gram	± 5.14 gram
Expiry date			31 May 2025

<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, 25 September 2024

M. Mennens / K. Amponsah

QA, Office of Medicinal Cannabis

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