

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:

24B12FP24C20

Order numbers:

containers: 385992 to 385993

bags:

385995

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

12 Feb 2024

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

20 Mar 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

30 May 2024 to 03 Jun 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

General analysis

Heembadweg 5

Analysis number: 48081 Report date: 20 Mar 2024

NL-9561 CZ Ter Apel

Microbiology of end product in container

Analysis number: 49616 Report date: 26 Jun 2024

Testing method:

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

Method

Specification

Result

Characters

Monograph

Odour characteristic for Cannabis flower. Does

not contain stalks that

Conform

are longer than 2.0 cm and only 20% of the stalks are between 1.5

and 2.0 cm

Identification

characters

Macroscopic botanical

Visual

Brown, green

granulates of flowers of

Conform

about 4 to 6 mm in

diameter

Microscopic botanical

Monograph

Gland hairs are mainly

characters

observed

Conform

Thin-layer chromatography Ph. Eur. (current ed.)

2.2.27, Monograph

Comparable with reference

Conform

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

24B12FP24C20			
Foreign material	Visual	Free from insects and other vermin	Conform
Microbial contamination Total aerobic microbial count (TAMC)	Ph. Eur. (current ed.) 2.6.12, 2.6.13	≤10² cfu/gram	< 10² cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	< 10 ¹ cfu/gram
S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria		Absent (1 gram)	Conform
Aflatoxins	Monograph		
Aflatoxin B ₁		≤ 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.) 2.2.32	≤ 10.0 %	6.8 %
Assay (HPLC)	Ph. Eur. (current ed.		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2 – 16.8]	15.9 %
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 455	5 gram	± 5.14 gram
Expiry date			31Jan2025

^{*}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, 27 June 2024

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