

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:

24G15EY24H07

Order numbers:

containers: 386734

bags:

386735

Grower/drier:

Bedrocan Nederland B.V.

15 July 2024

harvest date/period:

P.O. Box 2009 NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

Soevereinstraat 2

date: 07 August 2024

dose: ≥ 10,0 kGy

Result

irradiation:

NL-4879 NN Etten-Leur

Fagron Nederland B.V.

date:

Packager:

Venkelbaan 101

11 October 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Method

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

Analysis number: 49915

Report date: 16 August 2024

Microbiology of end product in container 2.

> Analysis number: 51022 Report date: 28 October 2024

Testing method:

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

Specification

Characters	Monograph	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	conform
Identification			
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.) 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

24G15EY24H07

24G15EY24H07					
Foreign material	Visual	Free from insect other vermi		conform	
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10²	cfu/gram
Total combined		≤10¹ cfu/gra	m	< 10 ¹	cfu/gram
yeasts/moulds count (TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gra	im)	conf	orm
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins B ₁ , B ₂ ,		≤ 4 µg/kg			μg/kg
G₁ and G₂					
Pesticides	Ph. Eur. (current ed.) 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.) 2.2.32	≤ 10.0	%	9.7	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	19.3	%
Cannabidiol (CBD, total equivalent)		<1.0	%	0.2	%
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	gram	± 5.15 30 Jun	_

^{*}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, 30 Oct 2024

K. Amponsah / S. Vos- de Schipper QA, Office of Medicinal Cannabis