

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:

24C11EY24D17

Order numbers:

containers: 386108 to 386110

bags:

386112

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL- 9640 CA Veendam

11 Mar 2024

Gamma

Synergy Health Ede B.V.

date:

dose:

Result

irradiation:

Packager:

Soevereinstraat 2

17 Apr 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur Fagron Nederland B.V.

date:

Venkelbaan 101 NL-2908 KE Capelle a/d IJssel

05 - 10 Jun 2024

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

Method

General analysis 1.

> Analysis number: 48454 Report date: 16 Apr 2024

Microbiology of end product in container

Analysis number: 49620 Report date: 26 Jun 2024

Testing method:

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

Specification

	Mictiloa	Specification	nesure
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	

Address:

Ministry of Health, Welfare and Sport

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Our reference 24C11EY24D17

24C11EY24D17				
Foreign material	Visual	Free from insects and other vermin	Confo	rm
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ²	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)	Confo	orm
Aflatoxins	Monograph			
Aflatoxin B ₁		≤ 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.) 2.8.13	≤ Limits Ph. Eur. 2.8.13	* Confo	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 %	8.3	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 – 26.4	1] 19.3	%
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 Expiry date	BMC-SWV 455	5 gram	± 5.15 28Feb2025	gram

^{*}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