

Office of Medicinal Cannabis



Release certificate

Product:

Cannabis flos, variety Bediol (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 6.3%

cannabidiol: ca. 8%

Dosage form:

flowers

bags:

Package size:

5 grams in container, 400 grams in bags

Batch:

24C25FB24E01

Order numbers:

containers: 386151

386153

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 25 March 2024

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

dose:

Pocult

irradiation: Soevereinstraat 2

Venkelbaan 101

01 May 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

date:

28 June 2024 - 01 July 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

Mathod

1. General analysis

> Analysis number: 48620 Report date: 29 April 2024

Microbiology of end product in container

Analysis number: 49880 Report date: 25 July 2024

Testing method:

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

Specification

	ivietnoa	Specification	Result
Characters	Monograph	Odour characteristic for Cannabis flower, Does	Conform
		not contain stalks that are	
		longer than 2.0 cm and	
		only 20% of the stalks are	
		between 1.5 and 2.0 cm	
Identification			Conform
Macroscopic botanical	Visual	Brown, green granulates	
characters		of flowers of about 4 to 6	
		mm in diameter	
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	
Foreign material	Visual	Free from insects and	Conform
<u> </u>		other vermin	

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Ministry of Health, Welfare and Sport

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Our reference

24C25FB24E01				
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	<10¹	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
	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	Confe	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	
, ,	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	7.5	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.4	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.2	%
	Ph. Eur. (current ed.)			
	2.2.29, Monograph	≤ 1.0 %	< 0.1	%
Content of container Expiry date	BMC-SWV 455	5 gram	± 5.15 28 Feb.	

^{*}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, 29 July 2024

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