

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

Package size:

5 grams in container, 400 grams in bags

Batch:

24F10FB24G31

Order numbers:

containers: 386589 to 386592

bags:

386593

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

10 June 2024

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

31 July 2024

≥ 10,0 kGy

Soevereinstraat 2

NL-4879 NN Etten-Leur

Fagron Nederland B.V. Packager:

Venkelbaan 101

date:

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

General analysis 1.

04 Oct. 2024 - 14 Oct. 2024

Heembadweg 5 NL-9561 CZ Ter Apel Analysis number: 49853 Report date: 06 August 2024

Microbiology of end product in container Analysis number: 51000

Report date: 22 Oct. 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 are longer than 2.0 cm and only 20% of the stalks are	Conform
1-1		between 1.5 and 2.0 cm	0
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	
Causian material			Conform
Foreign material	Visual	Free from insects and	Conform
		other vermin	

Ministry of Health, Welfare and Sport

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Our reference 24F10FB24G31

24F10FB24G31				
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		≤10¹ cfu/gram	< 10¹	cfu/gram
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram- negative bacteria		Absent (1 gram)	Conf	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*	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 %	7.8	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.1	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.2	%
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	± 5.14 31 May	-

^{*}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, 24 October 2024

K. Amponsah / M. Mennens QA, Office of Medicinal Cannabis