

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:

24G01FB24G24

Order numbers:

containers: 386717 to 386719

bags:

Not applicable

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

01 July 2024

Gamma

NL-9640 CA Veendam Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

24 July 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

12 Nov. 2024 - 14 Nov. 2024

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis 1.

Analysis number: 49783

Report date: 30 July 2024

Microbiology of end product in container

Analysis number: 51350 Report date: 20 Nov. 2024

Testing method:

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

	Method	Specification	Result	
Characters	Monograph	Odour characteristic for	conform	
		Cannabis flower. Does		
		not contain stalks that are		
		longer than 2.0 cm and		
		only 20% of the stalks are		
		between 1.5 and 2.0 cm		nform nform nform
Identification				
Macroscopic botanical	Visual	Brown, green granulates		
characters		of flowers of about 4 to 6	conform	
		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	
		other vermin		

The Netherlands

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Page

Our reference

24G01FB24G24				
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		≤10¹ cfu/gram	< 10 ¹	cfu/gram
yeasts/moulds count				
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram-		Absent (1 gram)	conf	orm
negative bacteria				
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*	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 %	7.2	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	5.8	%
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	7.8	%
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			30 June	2025

^{*}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, 26 November 2024

K. Amponsah / M. Mennens

QA, Office of Medicinal Cannabis