

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:

23L25FB24A24

Order numbers:

containers: 385699

Grower/drier:

385709 Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 25 December 2023

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

24 January 2024

≥ 10,0 kGy

Packager:

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

date:

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis 1.

22 March 2024 - 25 March 2024

Analysis number: 47458 Report date: 23 January 2024

2. Microbiology of end product in container

Analysis number: 48588 Report date: 10 April 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	
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	

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference 23L25FB24A24			
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)	conform
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*	conform
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 %	7.6 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	5.9 %
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.0 %
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 gram 30 Nov. 2024

^{*}The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl 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, 18 April 2024

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