

Release certificate

Product:

Cannabis flos, variety Bedrolite (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: < 1.0%

cannabidiol: ca. 7.5%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

23J02FR23K16

Order numbers:

containers: 385658 and 385659

bags:

385660

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 02 October 2023

NL- 9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

15 November 2023

≥ 10,0 kGy

rradiation: Soevereinstr

NL-4879 NN Etten-Leur

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Packager:

Fagron Nederland B.V.

date:

16 - 30 January 2024

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

Venkelbaan 101

NL-9561 CZ Ter Apel

1. General analysis

Analysis number: 46516

Report date: 20 November 2023

2. Microbiology of end product in container

Analysis number: 47810

Report date: 09 February 2024

Testing method:

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

	Method	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			
Macroscopic botanical	Visual	Brown, green granulates	
characters		of flowers of about 4 to 6 mm in diameter	conform
Microscopic botanical characters	Monograph	Gland hairs are mainly observed	conform
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	

Telefax +31 70 340 7426

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

23J02FR23K16					
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/gra	m	< 10 ¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin B ₁		≤ 2 µg/kg			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	%	6.7	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	< 1.0	%	0.4	%
(THC, total equivalent)					
Cannabidiol (CBD, total equivalent)		7.5 % [6	5.0 – 9.0]	8.5	%
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	0.1	%
equivalent)					
Content of container	BMC-SWV 455	5	gram	± 5.14	gram
Expiry date				31 Oct.	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, 07 March 2024

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