

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:

22I19FR22K09

Order numbers:

containers: 383553 to 383554

bags:

383556

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 19 September 2022

NL-9640 CA Veendam

Gamma irradiation:

Packager:

Synergy Health Ede B.V.

Soevereinstraat 2

date: 09 November 2022 dose: ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Fagron B.V.

date:

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

> Analysis number: 39802 Report date: 31 October 2022

Microbiology of end product in container

Analysis number: 41351

21 December - 22 December 2022

Report date: 10 January 2023

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	

The Netherlands

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Page 2

Our reference 22I19FR22K09					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram	1 <	10 ²	cfu/gram
count (TAMC)					
Total combined		≤10¹ cfu/gram	1 <	: 10¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram) conform		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.)	≤ Limits Ph. Eur. 2.	0 12*	conform	
	2.8.13	S LIIIIIIS FII. EUI. 2.	0.13"	COM	31111
Heavy metals	Ph. Eur. (current ed.)				
Lead	2.4.27, 2.2.58	max. 20.0 p	opm	< 5	ppm
Cadmium		max. 0.5 p	opm < 0.	125	ppm
Mercury		max. 0.5 p	opm < 0.	125	ppm
Loss on drying	Ph. Eur. (current ed.)	≤ 10.0 %	%	6.9	%
	2.2.32				
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	< 1.0	%	0.3	%
(THC, total equivalent)					
Cannabidiol (CBD, total		7.5 % [6.0	9.0]	7.3	%
equivalent)					
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0 %	% <	0.1	%
equivalent)					
Content of container	BMC-SWV 360	5 (gram ± !	5.14	gram
Expiry date			- N	lov.	2023

^{*}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.

ague, the Netherland January 2023

Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis

Dr. M.J. van de Velde