

## 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:

23B20FR23D26

Order numbers:

containers: 384618 to 384619

bags:

not available

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 20 February 2023

NL-9640 CA Veendam

Synergy Health Ede B.V.

date:

dose:

Gamma irradiation:

Soevereinstraat 2

26 April 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V.

date:

Venkelbaan 101

05 June 2023 - 06 June 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5 NL-9561 CZ Ter Apel

General analysis 1.

Analysis number: 42681 Report date: 11 April 2023

Microbiology of end product in container

Analysis number: 44225 Report date: 22 June 2023

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 between 1.5 and 2.0 cm	conform
Identification		between 1.5 and 2.0 cm	
Macroscopic botanical characters	Visual	Brown, green granulates 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.) 2.2.27, Monograph	Comparable with reference	conform
Foreign material	Visual	Free from insects and other vermin	conform

The Netherlands

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 23B20FR23D26				
	Die Ferri (aussent auf.)			
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram	< 10 <sup>2</sup> cf	u/gram
count (TAMC)		<101 of //	. 101 -4	/
Total combined		≤10¹ cfu/gram	< 10 <sup>1</sup> cf	u/gram
yeasts/moulds count				
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram- negative bacteria		Absent (1 gram)	confor	m
Aflatoxins	Monograph			
Aflatoxin B₁		≤ 2 µg/kg	< 2.0 μς	g/kg
Sum of aflatoxins $B_1$ , $B_2$ ,		≤ 4 µg/kg	< 4.0 µg	g/kg
$G_1$ and $G_2$				
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.	13* conform	m
Heavy metals	Ph. Eur. (current ed.)			
Lead	2.4.27, 2.2.58	max. 20.0 pp	m < 5 pp	pm
Cadmium		max. 0.5 pp	m < 0.125 pp	pm
Mercury		max. 0.5 pp	m < 0.125 pp	pm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	8.4 %	
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol	2.2.29, Monograph	< 1.0 %	0.3 %	

7.5 % [6.0 - 9.0]

≤ 1.0 %

5 gram

7.0 %

< 0.1 %

± 5.14 gram

30 April 2024

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, 27 June 2023

(THC, total equivalent)
Cannabidiol (CBD, total

Cannabinol (CBN, total

Related substances (HPLC) Ph. Eur. (current ed.)

2.2.29, Monograph

BMC-SWV 360

equivalent)

equivalent)
Content of container

Expiry date

K. Amponsah / R.V. Goormachtigh QA, Office of Medicinal Cannabis

<sup>\*</sup>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.