

Release certificate

Product:

Cannabis flos, variety Bedica (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 14%

cannabidiol: < 1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

24H12FP24I11

Order numbers:

containers: 386780 to 386781

386782

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 12 Aug. 2024

NL-9640 CA Veendam

Gamma

Packager:

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

11 Sep. 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Fagron Nederland B.V.

date:

Venkelbaan 101

28 - 31 Oct 2024

Laboratory:

NL-2908 KE Capelle a/d IJssel Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

> Analysis number: 50373 Report date: 18 Sep. 2024

Microbiology of end product in container

Analysis number: 51255 Report date: 13 Nov 2024

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				
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	

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference 24H12FP24I1

24H12FP24l11					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gra	ım	< 10 ²	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gra	m ,	< 10 ¹	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa, bile-tolerant gram-		Aboont (1 are	. ma. l	conf	
negative bacteria		Absent (1 gra	1111)	COIII	OIIII
Aflatoxins	Monograph				
Aflatoxin B₁		≤ 2 µg/kg		< 2.0	µg/kg
Sum of aflatoxins B ₁ , B ₂ ,		≤ 4 µg/kg		< 4.0	µg/kg
G₁ and G₂					
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	0.10		ppm
Cadmium		max. 0.5		< 0.125	25.00
Mercury		max. 0.5		< 0.125	
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0	%	7.8	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.:	2 – 16.8]	12.4	%
Cannabidiol (CBD, total equivalent)		<1.0	%	0.2	%
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	± 5.15	gram
Expiry date				31 Jul.	2025
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^{*}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, 15 Nov. 2024

S. Vos- de Schipper / M. Mennens QA, Office of Medicinal Cannabis