

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:

24G15FP24H07

Order numbers:

containers: 386585 to 386586

bags:

386588

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

15 Jul. 2024

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation: Soevereinstraat 2

07 Aug. 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

02 Oct. - 04 Oct. 2024

Venkelbaan 101

Laboratory:

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

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

> Analysis number: 49914 Report date: 16 Aug. 2024

Microbiology of end product in container

Analysis number: 50912 Report date: 15 Oct. 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			Conform
Macroscopic botanical characters	Visual	Brown, green granulates of flowers of about 4 to 6 mm in diameter	
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 24G15FP24H07					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gra	m	< 10 ²	cfu/gram
count (TAMC)					
Total combined		≤10¹ cfu/gra	m	< 10 ¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gra	ım)	Conf	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.) 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	nnm	- 5	ppm
Cadmium	2.4.27, 2.2.00	max. 0.5		< 0.125	
Mercury		max. 0.5		< 0.125	
Loss on drying	Ph. Eur. (current ed.)	≤ 10.0	1.1	7.0	
2000 on arying	2.2.32	_ 10.0	,,,	7.0	70
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol	2.2.29, Monograph	14 % [11.2	2 – 16.8]	15.5	%
(THC, total equivalent)					
Cannabidiol (CBD, total		<1.0	%	0.2	%
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 455	5	gram	± 5.14	gram
Expiry date				30 June	2025

^{*}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, 22 October 2024

M. Mennens / K. Amponsah QA, Office of Medicinal Cannabis