

Office of Medicinal Cannabis



Release certificate

Product:

Cannabis flos, variety Bedica (hemp flowers), granulated

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 14%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

24J07FP24J30

Order numbers:

containers: 386848 to 386850

bags:

not applicable

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

harvest date/period: 07 Oct 2024

NL-9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

30 Oct 2024

≥ 10,0 kGy

Packager:

NL-4879 NN Etten-Leur Fagron Nederland B.V.

date:

Venkelbaan 101

Laboratory:

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

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

06 - 10 Dec 2024

Analysis number: 51001 Report date: 05 Nov 2024

Microbiology of end product in container

cannabidiol: < 1.0%

Analysis number: 51682 Report date: 17 Dec 2024

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	

Ministry of Health, Welfare and Sport

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Our reference 24J07FP24J30			
Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ² cfu/gram
count (TAMC)			
Total combined		≤10¹ cfu/gram	< 10¹ cfu/gram
yeasts/moulds count			
(TYMC)			
S. aureus, P. aeruginosa,		About (1 gram)	conform
bile-tolerant gram-		Absent (1 gram)	COMOTH
<i>negative bacteria</i> Aflatoxins	Monograph		
Aflatoxin B ₁	Widnograph	≤ 2 µg/kg	< 2.0 µg/kg
		,	
Sum of aflatoxins B_1 , B_2 , G_1 and G_2		≤ 4 µg/kg	< 4.0 μg/kg
Pesticides	Ph. Eur. (current ed.)		
Pesticides	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 %	7.5 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2 – 16.8]	14.2 %
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 Expiry date	BMC-SWV 455	5 gram	± 5.15 gram 30 Sep 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, 07 January 2025

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