

## 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:

23C27FP23G05

Order numbers:

containers: 384931 to 384932

bags:

384935

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period: 27 March 2023

P.O. Box 2009

NL-9640 CA Veendam

date:

dose:

Gamma irradiation: Synergy Health Ede B.V.

Soevereinstraat 2 05 July 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date: 04 August 2023 - 09 August 2023

Venkelbaan 101

Laboratory:

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

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 43377 Report date: 09 May 2023

Microbiology of end product in container

Analysis number: 45197 Report date: 29 August 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	

Telefax +31 70 340 7426

The Netherlands

## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 23C27FP23G05				
Microbial contamination	Ph. Eur. (current ed.)			
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 <sup>2</sup>	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gram	< 101	cfu/gram
(TYMC)				
S. aureus, P. aeruginosa,				
bile-tolerant gram-		Absent (1 gram)	conform	
negative bacteria				
Aflatoxins	Monograph			
Aflatoxin B <sub>1</sub>		≤ 2 µg/kg	< 2.0	μg/kg
Sum of aflatoxins B1, B2,		≤ 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*	conf	orm
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 %	7.4	%
Assay (HPLC)	Ph. Eur. (current ed.)			
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2 – 16.8]	15.0	%
Cannabidiol (CBD, total equivalent)		<1.0 %	0.1	%
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	± 5.14	gram
Expiry date			31 July	-

<sup>\*</sup>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 September 2023

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