

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: **23E22FP23H09**Order numbers: containers: 385057
bags: 385059

Grower/drier: Bedrocan Nederland B.V. harvest date/period:

P.O. Box 2009 22 May 2023

NL- 9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 09 August 2023 \geq 10,0 kGy NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

Venkelbaan 101 04 September 2023 – 06 September 2023

NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V. 1. General analysis

Heembadweg 5 Analysis number: 44250 NL-9561 CZ Ter Apel Report date: 10 July 2023

Microbiology of end product in container

Analysis number: 45649

Report date: 21 September 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

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference 23E22FP23H09			
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	< 10 ¹ cfu/gram
yeasts/moulds count			
(TYMC)			
S. aureus, P. aeruginosa,			
bile-tolerant gram-		Absent (1 gram)	conform
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.)	≤ Limits Ph. Eur. 2.8.13*	conform
	2.8.13	2 Lilling 1 II. Lui. 2.0.15	Comonn
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.)	≤ 10.0 %	7.6 %
	2.2.32		
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol	2.2.29, Monograph	14 % [11.2 – 16.8]	12.3 %
(THC, total equivalent)			
Cannabidiol (CBD, total		<1.0 %	0.1 %
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	± 5.15 gram
Expiry date			31 Aug. 2024

^{*}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, 05 October 2023

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