Ministry of Health, Welfare and Sport





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: 24109FP24J02

Order numbers: containers: 386783 to 386784

> 386785 bags:

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

> P.O. Box 2009 09 Sep 2024

NL-9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 02 Oct 2024 ≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager: Fagron Nederland B.V. date:

> 23 - 28 Oct 2024 Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

Laboratorium Ofichem B.V. Laboratory:

General analysis Heembadweg 5 Analysis number: 50643 NL-9561 CZ Ter Apel Report date: 08 Oct 2024

1.

Microbiology of end product in container

Analysis number: 51172 Report date: 06 Nov 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

Address:

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Our reference 24I09FP24J02					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	< 10 ²	cfu/gram	
Total combined		≤10¹ cfu/gram	< 10 ¹	cfu/gram	
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)	conf	conform	
negative bacteria					
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	
G_1 and G_2					
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.1	3* conf	orm	
Heavy metals	Ph. Eur. (current ed.)				
Lead	2.4.27, 2.2.58	max. 20.0 ppr	n < 5	ppm	
Cadmium		max. 0.5 ppr	n < 0.125	ppm	
Mercury		max. 0.5 ppr	n < 0.125	ppm	
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	6.2	%	
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2 – 10	6.8] 13.8	%	
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 gra	m ± 5.15	gram	
Expiry date			31 Aug	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, 08 Nov 2024

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