

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%

cannabidiol: < 1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

23I25FP23K16

Order numbers:

containers: 385632 to 385634

385628 bags:

Grower/drier:

Bedrocan Nederland B.V.

P.O. Box 2009

25 September 2023

NL- 9640 CA Veendam

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

15 November 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Laboratory:

Fagron Nederland B.V.

03 - 05 January 2024

Venkelbaan 101

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

General analysis

harvest date/period:

Analysis number: 46311

Heembadweg 5 NL-9561 CZ Ter Apel

Report date: 13 November 2023

Microbiology of end product in container

Analysis number: 47656

Report date: 30 January 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	

The Netherlands

Ministry of Health, Welfare and Sport

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Our reference

23I25FP23K16					
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	<	10¹	cfu/gram
yeasts/moulds count					
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram))	confo	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.)	≤ Limits Ph. Eur. 2.8	8.13*	confo	orm
	2.8.13				
Heavy metals	Ph. Eur. (current ed.)				
Lead	2.4.27, 2.2.58	max. 20.0 p	•		ppm
Cadmium		max. 0.5 p			ppm
Mercury		max. 0.5 p			ppm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	Ď	7.7	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2 –	16.8]	11.9	%
Cannabidiol (CBD, total equivalent)		<1.0 %	ó	0.2	%
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	, o <	0.1	%
Content of container	BMC-SWV 455	5 g	ram ±!	5.15	gram
Expiry date					2024

^{*}The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxon-methyl 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 March 2024

K. Amponsah / S. Vos- de SchipperQA, Office of Medicinal Cannabis