

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Release certificate

Product:

Cannabis flos, variety Bedrocan (hemp flowers)

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 22%

cannabidiol: < 1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

23L11EY24B07

Order numbers:

containers: 385946 to 385956

Not applicable

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

NL-9640 CA Veendam

11 Dec. 2023

Gamma

Synergy Health Ede B.V.

date:

dose:

irradiation:

Soevereinstraat 2

07 Feb. 2024

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron Nederland B.V.

date:

Venkelbaan 101

NL-2908 KE Capelle a/d IJssel

25 April 2024 to 01 July 2024

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis

Analysis number: 47541 Report date: 29 Jan. 2024

2. Microbiology of end product in container

Analysis number: 49069 Report date: 14 May 2024

Testing method:

OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

Method

Specification

Result

Conform

Characters

Monograph

Odour characteristic for Cannabis flower. Leaves shoot out no more than 20% of the length of the flower and stalks are mostly cut off directly

under the bottom site of

the flowers

Identification

characters

Macroscopic botanical

Visual

Brown, green clustered

flowers of about 1.5 to

Conform

3.0 cm length

Microscopic botanical

Monograph

Gland hairs are mainly

Conform

characters

Thin-layer chromatography Ph. Eur. (current ed.)

observed

2.2.27, Monograph

Comparable with reference

Conform

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The Netherlands Telephone +31 70 340 5113 Telefax +31 70 340 7426

Address: Hoftoren Rijnstraat 50

NL-2515 XP THE HAGUE reference of this letter. The Netherlands

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Page 2

Our reference 23L11EY24B07

23L11EY24B07						
Foreign material	Visual	Free from insects and other vermin		Conf	Conform	
Microbial contamination	Ph. Eur. (current ed.)					
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram		< 10²	cfu/gram	
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gra	m	< 10¹	cfu/gram	
S. aureus, P. aeruginosa, bile-tolerant gram- negative bacteria		Absent (1 gram)		Conform		
Aflatoxins	Monograph					
Aflatoxin B ₁		≤ 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.) 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	%	6.9	%	
Assay (HPLC)	Ph. Eur. (current ed.)					
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6	6 – 26.4]	20.1	%	
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	± 5.15	gram	
Expiry date				30 Nov.	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, 15 July 2024

K. Amponsah / M .Mennens

QA, Office of Medicinal Cannabis