

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:

22H22EY22K09

Order numbers:

containers: 383541 to 383551

bags:

not applicable

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period: 29 August 2022

P.O. Box 2009

NL- 9640 CA Veendam

date:

Gamma

Synergy Health Ede B.V.

dose:

irradiation:

Soevereinstraat 2

09 November 2022

≥ 10,0 kGy

iraaration.

NL-4879 NN Etten-Leur

date:

Packager: Fagron B.V.

uate

Venkelbaan 101 NL-2908 KE Capelle a/d IJssel

04 January 2023 - 11 January 2023

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

1. General analysis

Analysis number: 39302 Report date: 04 October 2022

2. Microbiology of end product in container

Analysis number: 41492 Report date: 17 January 2023

Testing method:

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

	Method	Specification	Result
Characters	Monograph	Odour characteristic for	conform
		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			
Macroscopic botanical	Visual	Brown, green clustered	
characters		flowers of about 1.5 to	conform
		3.0 cm length	
Microscopic botanical characters	Monograph	Gland hairs are mainly observed	conform
Thin-layer chromatography	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	conform

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The Netherlands

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference 22H22EY22K09

22H22EY22K09			
Foreign material	Visual	Free from insects and other vermin	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		≤10¹ cfu/gram	<10¹ cfu/gram
(TYMC)			
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 ,		≤ 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*	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 %	8.7 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	22 % [17.6 – 26.4]	21.6 %
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 360	5 gram	± 5.14 gram
Expiry date			Nov. 2023

^{*}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, 20 January 2023

Dr. M.J. van de Velde

Head, Office of Medicinal Cannabis
Van de Velde