

Office of Medicinal Cannabis

## Release certificate

Product:

Cannabis flos, variety Bedrobinol (hemp flowers)

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: ca. 13.5%

cannabidiol: < 1.0%

Dosage form:

Package size:

5 grams in container, 400 grams in bags

Batch:

22K21FA23A11

Order numbers:

containers: 383988 to 383989

bags:

not available

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

21 November 2022

Gamma

NL-9640 CA Veendam Synergy Health Ede B.V.

NL-4879 NN Etten-Leur

date:

dose:

irradiation:

Soevereinstraat 2

11 January 2023

≥ 10,0 kGy

Packager:

Fagron B.V.

date:

Venkelbaan 101

19 January 2023

Laboratory:

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

General analysis 1.

Heembadweg 5 NL-9561 CZ Ter Apel Analysis number: 41081 Report date: 03 January 2023

Microbiology of end product in container Analysis number: 41780

Report date: 02 February 2023

Testing method:

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

Characters

Method

Specification

Result

conform

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

observed

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

Comparable with

conform

2.2.27, Monograph

reference

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## Ministry of Health, Welfare and Sport

## Office of Medicinal Cannabis

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Our reference 22K21FA23A11

2211211 A23A11					
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		< 10 <sup>2</sup>	cfu/gram
Total combined yeasts/moulds count		≤10¹ cfu/gra	m	< 10 <sup>1</sup>	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa,					
bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria					
Aflatoxins	Monograph				
Aflatoxin B₁		≤ 2 µg/kg			µg/kg
Sum of aflatoxins $B_1$ , $B_2$ ,		≤ 4 µg/kg		< 4.0	µg/kg
G₁ and G₂					
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	%	9.0	
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	13.5 % [10.8	3 – 16.2]	13.0	%
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	± 5.15 31 Jan.	_
Expiry date				o i Jaii.	2024

<sup>\*</sup>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, 03 February 2023

Head, Office of Medicinal Cannabis