

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:

23A02FP23C22

Order numbers:

containers: 384395 to 384396

bags:

384398

Grower/drier:

Bedrocan Nederland B.V.

harvest date/period:

P.O. Box 2009

02 Jan 2023

Gamma

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

date:

dose:

irradiation:

Soevereinstraat 2 22 Mar 2023

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron B.V.

date:

14 Apr 2023 - 19 Apr 2023

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

Venkelbaan 101

NL-9561 CZ Ter Apel

General analysis 1.

> Analysis number: 41711 Report date: 13 Feb 2023

Microbiology of end product in container

Analysis number: 43642 Report date: 09 May 2023

Testing method:

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

d.

Telefax +31 70 340 7426

Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

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Our reference

23A02FP23C22					
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 yeasts/moulds count		≤10¹ cfu/gram		≤10¹	cfu/gram
(TYMC)					
S. aureus, P. aeruginosa, bile-tolerant gram-		Absent (1 gram)		conform	
negative bacteria					
Aflatoxins	Monograph			April 1999	B
Aflatoxin B_1		≤ 2 µg/kg			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	%	5.7	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	14 % [11.2	2 – 16.8]	15.0	%
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	%	< 1.0	%
Content of container	BMC-SWV 360	5	gram	± 5.15	gram
Expiry date				31 Mar	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 May 2023

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

banjered