

Release certificate

Product: Cannabis flos, variety Bedrolite (hemp flowers), granulated

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: < 1.0% cannabidiol: ca. 7.5%

Dosage form: flowers

Package size: 5 grams in container, 400 grams in bags

Batch: 23B20FR23H09
Order numbers: containers: 385060

bags: 385062

Grower/drier: Bedrocan Nederland B.V. harvest date/period: P.O. Box 2009 20 February 2023

NL- 9640 CA Veendam

Gamma Synergy Health Ede B.V. date: dose: irradiation: Soevereinstraat 2 09 August 2023 \geq 10,0 kGy

NL-4879 NN Etten-Leur Packager: Fagron Nederland B.V.

ackager: Fagron Nederland B.V. date:

Venkelbaan 101 24 August 2023

NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V. 1. General analysis
Heembadweg 5 Analysis number: 42682

NL-9561 CZ Ter Apel Report date: 11 April 2023

Microbiology of end product in container

Analysis number: 45511

Report date: 13 September 2023
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

Characters	Method Monograph	Specification Odour characteristic for 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	Result conform
Identification Macroscopic botanical characters	Visual	Brown, green granulates of flowers of about 4 to 6 mm in diameter	conform
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
Foreign material	Visual	Free from insects and other vermin	conform

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Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Page
2
Our reference
23B20FR23H

Our reference					
23B20FR23H09					
Microbial contamination	Ph. Eur. (current ed.)				
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10² cfu/gram	1	< 10 ²	cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10¹ cfu/gram	1	< 10 ¹	cfu/gram
S. aureus, P. aeruginosa,					
bile-tolerant gram- negative bacteria		Absent (1 gram	n)	conf	orm
Aflatoxins	Monograph				
Aflatoxin B ₁	3112130000	≤ 2 µg/kg		< 2.0	μg/kg
Sum of aflatoxins B ₁ , B ₂ ,		≤ 4 µg/kg			μg/kg
G ₁ and G ₂		10 0			100
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.	8.13*	conf	orm
Heavy metals	Ph. Eur. (current ed.)				
Lead	2.4.27, 2.2.58	max. 20.0	opm	< 5	ppm
Cadmium		max. 0.5	opm	< 0.125	ppm
Mercury		max. 0.5 p	opm	< 0.125	ppm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0	%	8.6	%
Assay (HPLC)	Ph. Eur. (current ed.)				
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	< 1.0	%	0.3	%
Cannabidiol (CBD, total equivalent)		7.5 % [6.0	9.0]	6.4	%
Related substances (HPLC)	Ph. Eur. (current ed.)				
Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0 %	%	< 0.1	%

^{*}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.

5 gram

± 5.15 gram

31 Aug. 2024

BMC-SWV 455

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, 25 September 2023

K. Amponsah / R.V. Goormachtigh
QA, Office of Medicinal Cannabis

Content of container

Expiry date