Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Release certificate

Product:	**Cannabis flos, variety Bediol (hemp flowers), granulated**		
Country:	to be sold on the pharmaceutical market		
Strength:	tetrahydrocannabinol: ca. 6.3%	cannabidiol : ca. 8%	
Dosage form:	flowers		
Package size:	5 grams in container, 400 grams in bags		
Batch:	**21K15FB22B02**		
Order numbers:	containers: 381068 bags: 381072		
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam	harvest date/period: 15 November 2021	
Gamma irradiation:	Synergy Health Ede B.V. Soevereinstraat 2 NL-4879 NN Etten-Leur	date: 2 February 2022	dose: ≥ 10,0 kGy
Packager:	Fagron B.V. Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 3 – 4 March 2022	
Laboratory:	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel	1. General analysis Analysis number: 33902 Report date: 28 December 2021 2. Microbiology of end product in container Analysis number: 35951 Report date: 23 March 2022	
Testing method:	OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021		

	Method	**Specification**	**Result**
Characters	Monograph	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	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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Our reference
21K15FB22B02

Microbial contamination	Ph. Eur. (current ed.)		
Total aerobic microbial count (TAMC)	2.6.12, 2.6.13	≤10^2 cfu/gram	< 10^2 cfu/gram
Total combined yeasts/moulds count (TYMC)		≤10^1 cfu/gram	< 10^1 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 %	7.7 %
Assay (HPLC)	Ph. Eur. (current ed.)		
Tetrahydrocannabinol (THC, total equivalent)	2.2.29, Monograph	6.3 % [5.0 – 7.6]	6.0 %
Cannabidiol (CBD, total equivalent)		8.0 % [6.4 – 9.6]	8.0 %
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 gram
Expiry date			Jan. 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, 24 March 2022

Dr. M.J. van de Velde
Head, Office of Medicinal Cannabis

Dr. M.J. van de Velde