Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis

Release certificate

Product	**Cannabis flos, variety Bedrolite (hemp flowers) CBD-dominant type** to be prescribed to patients as a medicinal product		
Strength	tetrahydrocannabinol: ≤ 1.0%	cannabidiol: ≥ 5.0%	
Dosage form	flowers, granulated		
Package size and type	5 grams in container, 400 grams in bags		
Testing method	European Pharmacopoeia (Ph. Eur.) 07/2024:3028		
Batch	**25I01FR25I25**		
Order numbers	containers 387390 to 387391 bags not applicable		
Expiry date	31 Aug 2026		
Grower/drier	Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam	harvest date: 01 Sep 2025	
Gamma irradiation	Synergy Health Ede B.V. Soevereinstraat 2 NL-4879 NN Etten-Leur	date: 24 Sep 2025	dose: ≥ 10,0 kGy
Packager	Fagron Nederland B.V. Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 08 – 10 Oct 2025	
Laboratory	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel	1. General analysis Analysis number: 54552 Report date: 30 Sep 2025	
		2. Microbiology of end product in container Analysis number: 54891 Report date: 21 Oct 2025	

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Results of analysis

	Method	Specification	Result
Appearance	Visual	Dried, fragmented, fully developed female inflorescence of Cannabis sativa L. Stalks are no longer than 2.0 cm and only 20% of the stalks are between 1.5 and 2.0 cm.	Complies
Identification			
Macroscopic botanical characters	Monograph	Conform Identification A.	Complies
Microscopic botanical characters	Monograph	Conform Identification B.	Complies
High-performance thin-layer chromatography	Monograph	Comparable with reference and test solutions CBD-dominant type. Conform Identification C.	Complies
Loss on drying	Monograph	≤ 12.0%	8.8 %
		Maximum 2%	1 %
Foreign material	Monograph	It does not contain any seeds or other foreign elements and the whole herbal drug does not contain any leaves more than 1.0 cm in length.	Complies
Aflatoxins			
Aflatoxin B_1	Ph. Eur. (current ed.) 2.8.18	≤ 2 µg/kg	< 2 µg/kg
Sum of aflatoxins B_1, B_2, G_1 and G_2		≤ 4 µg/kg	< 4 µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	≤ Limits Ph. Eur. 2.8.13*	Complies
Heavy metals			
Arsenic	Monograph	≤ 0.2 ppm	< 0.1 ppm
Cadmium		≤ 0.3 ppm	< 0.2 ppm
Lead		≤ 0.5 ppm	< 0.3 ppm
Mercury		≤ 0.1 ppm	< 0.1 ppm
Assay (HPLC)			
Tetrahydrocannabinol (THC, total equivalent)	Monograph	≤ 1.0%	0.3 %
Cannabidiol (CBD, total equivalent)		≥ 5.0%	7.1 %

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Results of analysis

	Method	Specification	Result
Related substances (HPLC)			
Cannabinol (CBN, total equivalent)	Monograph	≤ 1.0%	< 0.1 %
Microbial contamination			
Total aerobic microbial count (TAMC)	Ph. Eur. (current ed.) 2.6.12, 2.6.13	$\leq 10^2$ cfu/gram	$< 10^2$ cfu/gram
Total combined yeasts/moulds count (TYMC)		$\leq 10^1$ cfu/gram	$< 10^1$ cfu/gram
S. aureus, P. aeruginosa, bile-tolerant gram-negative bacteria		Absent (1 gram)	Complies

**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, manufactured, gamma irradiated, packaged and tested in full compliance with the GACP and GMP requirements and with the specifications as stated in this document.

The Hague, the Netherlands, 30 October 2025

K. Amponsah / M. Mennens
QA, Office of Medicinal Cannabis