



Release certificate

Product	Cannabis flos, variety Bedrolite (hemp flowers) CBD-dominant type		
	to be prescribed to patients as a medicinal product		
Strength	tetrahydrocannabinol: $\leq 1.0\%$	cannabidiol: ca. 8.1%	
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	25E12FR25F04		
Order numbers	containers	387227, 387228	
	bags	387229	
Expiry date	30 April 2026		
Grower/drier	Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam	harvest date: 12 May 2025	
	Synergy Health Ede B.V. Soeverinstraat 2 NL-4879 NN Etten-Leur	date: 04 Jun. 2025	dose: $\geq 10,0$ kGy
Packager	Fagron Nederland B.V. Venkelbaan 101 NL-2908 KE Capelle a/d IJssel	date: 26 – 30 Jun. 2025	
	Laboratorium Ofichem B.V. Heembadweg 5 NL-9561 CZ Ter Apel	1.	General analysis Analysis number: 53485 Report date: 11 Jun. 2025
		2.	Microbiology of end product in container Analysis number: 53985 Report date: 22 Jul. 2025



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%	8.1 %
		Maximum 2%	2 %
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 µg/kg	< 2 µg/kg
Sum of aflatoxins B ₁ , B ₂ , G ₁ and G ₂	2.8.18	≤ 4 µg/kg	< 4 µg/kg
Pesticides	Ph. Eur. (current ed.)	≤ Limits Ph. Eur. 2.8.13*	Complies
	2.8.13		
Heavy metals			
Arsenic		≤ 0.2 ppm	< 0.1 ppm
Cadmium		≤ 0.3 ppm	< 0.2 ppm
Lead	Monograph	≤ 0.5 ppm	< 0.3 ppm
Mercury		≤ 0.1 ppm	< 0.1 ppm
Assay (HPLC)			
Tetrahydrocannabinol (THC, total equivalent)		≤ 1.0%	0.3 %
Cannabidiol (CBD, total equivalent)	Monograph	8.1% [6.5 – 9.7]%	8.4 %



Results of analysis

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

**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, 24 July 2025

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