Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



Release certificate

Product: Country:	Cannabis flos, variety Bedrolite (hemp flowers), granulated to be sold on the pharmaceutical market							
Strength:		drocannabinol: < 1.0%	cannabidiol: ca. 7.5%					
Dosage form:	flowers							
Package size:	5 grams in container, 400 grams in bags							
Batch:	24F24FR24G17							
Order numbers:	contain	containers: 386444						
	bags:	386445						
Grower/drier:	Bedroca P.O. Bo		harvest date/period: 24 Jun. 2024					
Gamma	NL- 9640 CA Veendam Synergy Health Ede B.V.		date: dose:					
irradiation:		einstraat 2	17 Jul. 2024 \geq 10,0 kGy					
inadiation.		9 NN Etten-Leur						
Packager: Fagron		Nederland B.V.	date:					
		baan 101	21 Aug. 2024					
	NL-2908	3 KE Capelle a/d IJssel						
Laboratory:	Laboratorium Ofichem B.V.		1. General analysis					
Heembad NL-9561 C		adweg 5	Analysis number: 49731					
		1 CZ Ter Apel	Report date: 23 Jul. 2024					
	2. Microbiology of end proc							
			Analysis number: 50560					
			Report date: 18 Sep. 2024					
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021								
		Method	Specification Result					
Characters		Monograph	Odour characteristic for Conform					
			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					
Identification			Conform					
<i>Macroscopic botanical</i> <i>characters</i>		Visual	Brown, green granulates					
			of flowers of about 4 to 6 mm in diameter					
		general begreater						
Microscopic botanical		Monograph	Gland hairs are mainly Conform					
characters			observed	Conton				
Thin-layer chroma	tography	Ph. Eur. (current ed.)	Comparable with Conform					
Foreign motorial		2.2.27, Monograph	reference					
Foreign material		Visual	Free from insects and Conform other vermin					

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All correspondence addressed to the postal address quoting date and NL-2515 XP THE HAGUE reference of this letter.

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	Our reference 24F24FR24G17					
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		≤10 ¹ cfu/gram		< 10 ¹	cfu/gram
	yeasts/moulds count (TYMC)					
	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 B1, B2, G1 and G2		≤ 4 µg/kg		< 4.0	µg/kg
	Pesticides	Ph. Eur. (current ed.)				
	resticides	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		< 0.125	
	Mercury		max. 0.5	ppm	< 0.125	ppm
	Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0	%	8.8	%
	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]		8.5	%
	Related substances (HPLC)	Ph. Eur. (current ed.)				
	Cannabinol (CBN, total equivalent)	2.2.29, Monograph	≤ 1.0	%	< 0.1	%
	Content of container Expiry date	BMC-SWV 455	5	gram	± 5.15 31 May	

*The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl 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, 19 September 2024

Anpensoh

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