

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:

23A23FR23D05

Order numbers:

containers: 384530 384531

Grower/drier:

bags: Bedrocan Nederland B.V.

harvest date/period: 23 January 2023

P.O. Box 2009

NL-9640 CA Veendam

dose:

Gamma

Synergy Health Ede B.V.

NL-4879 NN Etten-Leur

date:

≥ 10,0 kGy

irradiation:

Soevereinstraat 2

05 April 2023

Packager:

Fagron B.V.

date:

Venkelbaan 101

24 - 26 April 2023

Laboratory:

NL-2908 KE Capelle a/d IJssel Laboratorium Ofichem B.V.

Heembadweg 5

1. General analysis

Analysis number: 42118 Report date: 06 March 2023

NL-9561 CZ Ter Apel

Microbiology of end product in container

Analysis number: 43645 Report date: 09 May 2023

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					
Macroscopic botanical	Visual	Brown, green granulates			
characters		of flowers of about 4 to 6	conform		
		mm in diameter			
Microscopic botanical	Monograph	Gland hairs are mainly	conform		
characters		observed			
Thin-layer chromatography	Ph. Eur. (current ed.)	Comparable with	conform		
	2.2.27, Monograph	reference			
Foreign material	Visual	Free from insects and	conform		
		other vermin			

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	Our reference 23A23FR23D05						
	Microbial contamination	Ph. Eur. (current ed.)					
	Total aerobic microbial	2.6.12, 2.6.13	≤10² cfu/gram		≤10 ²	cfu/gram	
	count (TAMC)						
	Total combined		≤10¹ cfu/gram		≤10¹	cfu/gram	
	yeasts/moulds count						
	(TYMC)						
S. aureus, P. aeruginosa,							
	bile-tolerant gram-		Absent (1 gram)		conform		
	negative bacteria						
	Aflatoxins	Monograph					
	Aflatoxin B ₁		≤ 2 µg/kg		< 2.0	µg/kg	
	Sum of aflatoxins B ₁ , B ₂ ,		≤ 4 µg/kg		< 4.0	µg/kg	
	G_1 and G_2						
Pesticides		Ph. Eur. (current ed.)	≤ Limits Ph. Eur. 2.8.13*		conform		
		2.8.13	2 Emilio I II. Edi.	COIII	OTTT		
	Heavy metals	Ph. Eur. (current ed.)					
	Lead	2.4.27, 2.2.58	max. 20.0	5 5	< 5	ppm	
	Cadmium		max. 0.5	ppm	< 0.125	ppm	
	Mercury		max. 0.5	ppm	< 0.125		
	Loss on drying	Ph. Eur. (current ed.)	≤ 10.0	%	7.8	%	
		2.2.32					
	Assay (HPLC)	Ph. Eur. (current ed.)					
	Tetrahydrocannabinol	2.2.29, Monograph	< 1.0	%	0.3	%	
	(THC, total equivalent)						
	Cannabidiol (CBD, total equivalent)		7.5 % [6	5.0 – 9.0]	8.1	%	
	Related substances (HPLC)	Ph. Eur. (current ed.)					
	Cannabinol (CBN, total	2.2.29, Monograph	≤ 1.0	%	< 0.1	%	
	equivalent)						
	Content of container	BMC-SWV 360	5	gram	± 5.14		
	Expiry date				30 April	2024	

^{*}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, 16 May 2023

K. Amponsah / S. Vos- de Schipper QA, Office of Medicinal Cannabis