

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: approx. 6.3%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

21I06FB21J20

Order numbers:

containers: 380057 and 380058

380066 bags:

Grower/drier:

Bedrocan B.V.

P.O. Box 2009

harvest date/period: 6 September 2021

NL-9640 CA Veendam

Gamma irradiation:

Synergy Health Ede B.V.

date:

dose:

cannabidiol: approx. 8%

Soevereinstraat 2

20 October 2021

≥ 10,0 kGy

NL-4879 NN Etten-Leur

Packager:

Fagron B.V.

date:

Venkelbaan 101

4 - 9 November 2021

NL-2908 KE Capelle a/d IJssel

Laboratory:

Laboratorium Ofichem B.V.

Heembadweg 5

NL-9561 CZ Ter Apel

General analysis

Analysis number: 32476 Report date: 18 October 2021

Microbiology of end product in container

Analysis number: 33440

Report date: 23 November 2021

Testing method:

Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014

	Method	Specification	Result
Appearance	monograph	brown green granulated material of the flowers (about 5 mm) with a characteristic smell	conform
Identity			
microscopy	monograph	mainly gland hairs visible	conform
thin layer chromatography	monograph	monograph	conform
Foreign material	monograph	insects and other vermin are	conform
Fineness	Monograph	absent fine granulated flowers without stalks longer than 2.0 cm. Only 20% of the stalks is between 1.5 and 2.0 cm	conform

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Page 2 Our reference 21I06FB21J20



Z 11001 BZ 10Z0					
	Method	Specific	ation	Res	sult
Microbiological purity	Ph. Eur (current ed.)				
	5.1.4.				
Total aerobic microbial count (TAMC)	5.1.41.	≤10² cfu	ı/gram	< 10 <sup>2</sup>	cfu/gram
Total yeast and moulds count (TYMC)	5.1.41.	≤10¹ cfu	ı/gram	< 10 <sup>1</sup>	cfu/gram
P. aeruginosa, S.aureus	5.1.41.	ahaa	und.		conform
and Bile tolerant gram neg bacteria		abse	ent		contorm
Absence of aflatoxins	Ph. Eur (current ed.)				
	"Determination of				
	aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub>	≤ 4 µg	ı/kg	< 4.0	μg/kg
	and G <sub>2</sub> in herbal				
	drugs" (2.8.18)				
Absence of pesticides	Ph. Eur (current ed.)				
	"Pesticide residues"	≤ Limits Ph. E	Eur 2.8.13*	conf	form
	(2.8.13)				
Absence of heavy metal	Ph. Eur (current ed.)				
lead	"Heavy metals in	max. 20.0	ppm	< 5	ppm
mercury	herbal drugs and	max. 0.5		< 0.125	
cadmium	fatty oils"	max. 0.5	77. 75.	< 0.125	
	(monograph)				
Loss on drying	Ph. Eur (current ed.)	≤ 10.0	%	8.7	%
	"Loss on drying"				
	meth. C (2.2.32)				
Assay (HPLC)	,				
tetrahydrocannabinol(THC)	monograph	approx. 6.3	%	6.2	%
cannabidiol (CBD)	monograph	approx. 8		8.3	
Related substances (HPLC)	monograph	арргол. о	,,	0.0	,,
cannabinol (CBN)	monograph	< 1.0	%	< 0.1	%
Content of container	BMC-SWV 320	approx. 5		± 5.15	
Expiry date	2.110 0111 020	арргол. О	gram		2022

\*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 November 2021

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