

Ministry of Health, Welfare and Sport Office of Medicinal Cannabis

Release certificate

Product:

Cannabis flos, variety Bedrocan (hemp flowers)

Country:

to be sold on the pharmaceutical market

Strenath:

tetrahydrocannabinol: approx. 22%

cannabidiol: <1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

20H24EY20K04

Order numbers:

containers: 374658 to 374666

bags:

374657

Grower/drier:

Bedrocan B.V.

harvest date/period:

P.O. Box 2009

NL- 9640 CA Veendam

24 August 2020

Gamma irradiation:

Synergy Health Ede B.V.

date:

dose:

Soevereinstraat 2

NL-4879 NN Etten-Leur

4 November 2020

≥ 10,0 kGy

Packager:

Fagron B.V.

date:

Venkelbaan 101

19 - 27 November 2020

General analysis

Laboratory:

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

1.

Heembadweg 5

Analysis number: 26305

Report date: 10 November 2020

NL-9561 CZ Ter Apel

Microbiology of end product in container

Analysis number: 26904

Report date: 12 January 2021

Testing method:

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

2.

	Method	Specification	Result
Appearance	monograph	brown green clustered	conform
		flowers of 1,5 to 3 cm with a	
		characteristic smell	
Identity			
microscopy	monograph	mainly gland hairs visible	conform
thin layer chromatography	monograph	monograph	conform
Foreign material	monograph	insects and other vermin are	conform
		absent	
Fineness	monograph	 no leaves shooting out more than 20% of the length of the flowers stalks are cut away directly under the bottom flowers of the inflorescence 	conform

The Netherlands

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20H24EY20K04					
Microbiological purity	Ph. Eur (current ed.) 5.1.4.				
Total aerobic microbial count (TAMC)	5.1.41.	≤10² cfu	/gram	< 33	cfu/gram
Total yeast and moulds count (TYMC)	5.1.41.	≤10 cfu/	gram	< 7	cfu/gram
P. aeruginosa, S.aureus and Bile tolerant gram neg bacteria	5.1.41.	abse	nt		conform
Absence of aflatoxines	Ph. Eur (current ed.) "Determination of aflatoxins B ₁ , B ₂ , G ₁ and G ₂ in herbal drugs" (2.8.18)	≤ 4 µg	/kg	< 4.0	μg/kg
Absence of pesticides	Ph. Eur (current ed.) "Pesticide residues" (2.8.13)	≤ Limits Ph. E	Eur 2.8.13*	conf	orm
Absence of heavy metals	Ph. Eur (current ed.)				
lead	"Heavy metals in	max. 20.0	ppm	< 5	ppm
mercury	herbal drugs and	max. 0.5	ppm	< 0.125	ppm
cadmium	fatty oils" (monograph)	max. 0.5	ppm	< 0.125	ppm
Loss on drying	Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%	8.3	%
Assay (HPLC)					
tetrahydrocannabinol(THC)	monograph	approx. 22		21.6	
cannabidiol (CBD) Related substances (HPLC)	monograph	< 1.0	%	0.1	%
cannabinol (CBN)	monograph	< 1.0	%	< 0.1	%
Content of container Expiry date	BMC-SWV 320	approx. 5	gram	± 5.15 11 /	gram 2021

*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, 13 January 2021

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

Dr. M.J. van de Velde