Ministry of Health, Welfare and Sport





Release certificate

Product:

Cannabis flos, variety Bedrocan (hemp flowers)

Country:

to be sold on the pharmaceutical market

Strength:

tetrahydrocannabinol: approx. 22%

cannabidiol: <1.0%

Dosage form:

flowers

Package size:

5 grams in container, 400 grams in bags

Batch:

20C02EY20D01

Order numbers:

containers: 369276 to 369287

bags:

not available

Grower/drier:

Bedrocan BV

P.O. Box 2009

harvest date/period: 24 February 2020

NL-9640 CA Veendam

NL-4879 NN Etten-Leur

Gamma irradiation:

Synergy Health

date:

dose:

Soevereinstraat 2

1 April 2020

≥ 10,0 kGy

Packager:

Fagron BV

Venkelbaan 101

date:

Part of analysis:

NL-2908 KE Capelle a/d IJssel

4 - 13 May 2020

1. general analysis

2.microbiology of end product in

container

Laboratories:

Laboratorium Ofichem B.V. 1.

Heembadweg 5

NL-9561 CZ Ter Apel

2. Bactimm BV

> Middenkampweg 17 NL-6545 CH Nijmegen

Analysis number:

1.23340

2. AAH76633

Report date:

1. 27 March 2020

2. 18 May 2020

Testing method:

End check:

Analytical monograph by BMC / Farmalyse, version 7.1, Nov. 28, 2014 Office of Medicinal Cannabis

date: 19 May 2020

	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	stalks, insects and other	conform	
		vermin are absent		
Fineness	monograph	no leaves shooting out	conform	
		more than 20% of the length of the flowers		
		stalks are cut away		
		directly under the bottom		
		flowers of the		
		inflorescence		

The Netherlands

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Page 2 Our reference 20C02EY20D01



	Method	Specific	ation	Res	sult
Microbiological purity	Ph. Eur (current ed.) 5.1.4.				
Total aerobic microbial count (TAMC)	5.1.41.	≤10² cfu/gram		<10	cfu/gram
Total yeast and moulds count (TYMC)	5.1.41.	≤10 cfu/gram		<10	cfu/gram
P. aeruginosa, S.aureus and Bile tolerant gram neg bacteria	5.1.41.	absent			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	monograph	Ph. Eur (current ed.) 2.8.13			conform
Absence of heavy metal	BL Estate and all				
lead	Ph. Eur (current ed.)	max. 20.0	18.1 -		ppm
mercury cadmium	"Heavy metals in herbal drugs and fatty oils"	max. 0.5 max. 0.5		< 0.125 < 0.125	2 2
Loss on drying	(monograph) Ph. Eur (current ed.) "Loss on drying" meth. C (2.2.32)	≤10.0	%	7.9	%
Assay (HPLC)					
fingerprint	monograph	similar			conform
tetrahydrocannabinol(THC)	monograph	approx. 22	%	24.8	%
cannabidiol (CBD) Related substances (HPLC)	monograph	< 1.0	%	< 0.1	%
cannabinol (CBN)	monograph	< 1.0	%	< 0.05	
Content of container Expiry date	BMC-SWV 320	approx. 5	gram	± 5,14 04 /	gram 2021

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 May 2020

Dr. M.J. van de Velde

Dhead Office of Medicinal Cannabis