



Release certificate

Product: **Cannabis flos, variety Bedrolite (hemp flowers), granulated**

Country: to be sold on the pharmaceutical market

Strength: tetrahydrocannabinol: < 1.0% cannabidiol: approx. 7.5%

Dosage form: flowers

Package size: 5 grams in container, 400 grams in bags

Batch: **20J19FR21115**

Order numbers: containers: 379632 and 379633
bags: not available

Grower/drier: Bedrocan BV harvest date/period:
P.O. Box 2009 19 October 2020
NL- 9640 CA Veendam

Gamma irradiation: Synergy Health Ede B.V. date: dose:
Soeverinstraat 2 15 September 2021 ≥ 10,0 kGy
NL-4879 NN Etten-Leur

Packager: Fagron BV date:
Venkelbaan 101 12 – 14 October 2021
NL-2908 KE Capelle a/d IJssel

Laboratory: Laboratorium Ofichem B.V. 1. General analysis
Heembadweg 5 Analysis number: 26505
NL-9561 CZ Ter Apel Report date: 30 November 2020
2. Microbiology of end product in container
Analysis number: 33123
Report date: 28 October 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			
<i>microscopy</i>	monograph	mainly gland hairs visible	conform
<i>thin layer chromatography</i>	monograph	monograph	conform
Foreign material	monograph	insects and other vermin are absent	conform
Fineness	monograph	stalks are not longer than 2,0 cm and only 20% of the stalks is between 1,5 and 2,0 cm	conform



Page

2

Our reference
20J19FR21115

Microbiological purity	Ph. Eur (current ed.)		
	5.1.4.		
<i>Total aerobic microbial count (TAMC)</i>	5.1.4.-1.	≤ 10 ² cfu/gram	< 10 ² cfu/gram
<i>Total yeast and moulds count (TYMC)</i>	5.1.4.-1.	≤ 10 ¹ cfu/gram	< 10 ¹ cfu/gram
<i>P. aeruginosa, S.aureus and Bile tolerant gram neg bacteria</i>	5.1.4.-1.	absent	Conform
Absence of aflatoxins	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. Eur 2.8.13*	Conform
Absence of heavy metals	Ph. Eur (current ed.)		
<i>lead</i>	"Heavy metals in herbal drugs and fatty oils" (monograph)	max. 20.0 ppm	< 5 ppm
<i>mercury</i>		max. 0.5 ppm	< 0.125 ppm
<i>cadmium</i>		max. 0.5 ppm	< 0.125 ppm
Loss on drying	Ph. Eur (current ed.)		
	"Loss on drying" meth. C (2.2.32)	≤ 10.0 %	7.9 %
Assay (HPLC)			
<i>tetrahydrocannabinol(THC)</i>	monograph	< 1.0 %	0.3 %
<i>cannabidiol (CBD)</i>	monograph	approx. 7.5 %	7.1 %
Related substances (HPLC)			
<i>cannabinol (CBN)</i>	monograph	< 1.0 %	< 0.1 %
Content of container	BMC-SWV 320	approx. 5 gram	± 5.15 gram
Expiry date			09 / 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, 5 November 2021

Dr. M.J. van de Velde

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