



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: 24G08FR24G31
Order numbers: Containers: 386447
bags: 386446
Grower/drier: Bedrocan Nederland B.V. harvest date/period:
P.O. Box 2009 08 July 2024
NL- 9640 CA Veendam
Gamma irradiation: Synergy Health Ede B.V. date: dose:
Soeverestraat 2 31 July 2024 ≥ 10,0 kGy
NL-4879 NN Etten-Leur
Packager: Fagron Nederland B.V. date:
Venkelbaan 101 21 Aug. 2024 to 22 Aug. 2024
NL-2908 KE Capelle a/d IJssel
Laboratory: Laboratorium Ofichem B.V. 1. General analysis
Heembadweg 5 Analysis number: 49851
NL-9561 CZ Ter Apel Report date: 06 Aug. 2024
2. Microbiology of end product in container
Analysis number: 50652
Report date: 24 Sept. 2024
Testing method: OMC Monograph Cannabis Flower / Version 8.0 / November 01, 2021

	Method	Specification	Result
Characters	Monograph	Odour characteristic for 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	Conform
Identification			Conform
<i>Macroscopic botanical characters</i>	Visual	Brown, green granulates of flowers of about 4 to 6 mm in diameter	
<i>Microscopic botanical characters</i>	Monograph	Gland hairs are mainly observed	Conform
<i>Thin-layer chromatography</i>	Ph. Eur. (current ed.) 2.2.27, Monograph	Comparable with reference	Conform
Foreign material	Visual	Free from insects and other vermin	Conform



Microbial contamination	Ph. Eur. (current ed.)		
<i>Total aerobic microbial count (TAMC)</i>	2.6.12, 2.6.13	$\leq 10^2$ cfu/gram	$< 10^2$ cfu/gram
<i>Total combined yeasts/moulds count (TYMC)</i>		$\leq 10^1$ cfu/gram	$< 10^1$ cfu/gram
<i>S. aureus, P. aeruginosa, bile-tolerant gram-negative bacteria</i>		Absent (1 gram)	Conform
Aflatoxins	Monograph		
<i>Aflatoxin B₁</i>		≤ 2 µg/kg	< 2.0 µg/kg
<i>Sum of aflatoxins B₁, B₂, G₁ and G₂</i>		≤ 4 µg/kg	< 4.0 µg/kg
Pesticides	Ph. Eur. (current ed.) 2.8.13	$\leq$ Limits Ph. Eur. 2.8.13*	Conform
Heavy metals	Ph. Eur. (current ed.)		
<i>Lead</i>	2.4.27, 2.2.58	max. 20.0 ppm	< 5 ppm
<i>Cadmium</i>		max. 0.5 ppm	< 0.125 ppm
<i>Mercury</i>		max. 0.5 ppm	< 0.125 ppm
Loss on drying	Ph. Eur. (current ed.) 2.2.32	≤ 10.0 %	7.7 %
Assay (HPLC)	Ph. Eur. (current ed.)		
<i>Tetrahydrocannabinol (THC, total equivalent)</i>	2.2.29, Monograph	< 1.0 %	0.3 %
<i>Cannabidiol (CBD, total equivalent)</i>		7.5 % [6.0 – 9.0]	6.9 %
Related substances (HPLC)	Ph. Eur. (current ed.)		
<i>Cannabinol (CBN, total equivalent)</i>	2.2.29, Monograph	≤ 1.0 %	< 0.1 %
Content of container	BMC-SWV 455	5 gram	± 5.15 gram
Expiry date			30 June 2025

*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, 25 September 2024

 

K. Amponsah / M. Mennens

QA, Office of Medicinal Cannabis