

RELEASE CERTIFICATE
Certificate of Analysis - Certificate of Compliance

Product: Medizinal Cannabisblüten Pedanios 16/1 TNG-CA
Batch: E255
Expiry date: 05/2025
Strength: Dronabinol (THC): approx. 16 %
 Cannabidiol (CBD): < 1.0 %
Dosage Form: Dried Flowers
Destination: Germany
Package size: 10 grams

Manufacturer: Aurora Cannabis Enterprises Inc.
 River - 100 Reagens Industrial Parkway, Bradford West Gwillimbury, Ontario, L3Z 0Z8, Canada

Batch Release: Aurora Deutschland GmbH
 Hauptstr. 90
 D-12159 Berlin
 GMP Certificate No.: DE_BE_01_GMP_2023_0057

Irradiation Site: Sterigenics, Canada

Testing method: DAB Monograph "Cannabisblüten" (current edition)
 Ph.Eur. Monograph <1433> "Herbal Drugs" (current edition)

Storage: Tightly closed, protected from light, below 25 °C.

I hereby certify that the information is authentic and accurate. This batch of product has been produced, including packaging and quality control, in full compliance with GMP requirements and with the specifications as stated in this document. The batch processing, packaging and analysis records were reviewed and found to be in full compliance with GMP.	
Berlin, 05. DEZ. 2024	Sven Lehsing Qualified Person/Sachkundige Person nach § 14 AMG

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Product: Medizinal Cannabisblüten Pedanios 16/1 TNG-CA
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Parameter	Method	Specification	Result
Characteristics	DAB Cannabis flos (Characteristics)	Characteristic smell	Complies
Identity ¹			
appearance	DAB Cannabis flos (Identity A)	Comply with monograph	Complies
microscopy	DAB Cannabis flos (Identity B)	Comply with monograph	Complies
thin layer chromatography	DAB Cannabis flos (Identity C), Ph.Eur. 2.2.27	Comply with monograph	Complies
Purity			
Foreign material ¹	DAB Cannabis flos, Ph.Eur. 2.8.2	≤ 2 %	Complies
Loss on Drying ¹	DAB Cannabis flos, Ph.Eur. 2.2.32	≤ 10 %	8.7 %
Pesticides ¹	Ph.Eur. 2.8.13	Comply with Ph.Eur. 2.8.13	Complies
Absence of heavy metals ²	Ph.Eur. 2.4.27		
Lead		≤ 5 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Cadmium		≤ 1 ppm	< 0.05 ppm
Aflatoxins ¹	Ph.Eur. 2.8.18		
Aflatoxin B1		≤ 2 ppb	< 0.5 ppb
Sum of Aflatoxins B1, B2, G1, G2		≤ 4 ppb	< 1.0 ppb
Microbiological purity ²	Ph.Eur. 2.6.31	Comply with Ph.Eur. 5.1.8 B	
Total aerobic microbial count (TAMC)		≤ 10 ⁴ cfu/g (max. 50 000 cfu/g)	< 10 000 cfu/g
Total yeast and molds count (TYMC)		≤ 10 ² cfu/g (max. 500 cfu/g)	< 10 cfu/g
Bile-tolerant Gram-negative bacteria (BTGN)		≤ 10 ² cfu/g	< 10 cfu/g
E. coli		Absent in 1 g	Absent in 1 g
Salmonella		Absent in 25 g	Absent in 25 g
Related substance ¹ Cannabinol (CBN)	DAB Cannabis flos, Ph.Eur. 2.2.29	≤ 1.0 %	< 0.1 %
Assay ¹			
Dronabinol (THC)	DAB Cannabis flos, Ph.Eur. 2.2.29	14.4 – 17.6 %	14.5 %
Cannabidiol (CBD)	Ph.Eur. 2.2.29	< 1.0 %	< 0.1 %

* Batch-specific testing can be replaced by regular monitoring based on risk.

Testing Sites:

¹ Quality Services International GmbH, Bremen; ² BAV-Institut für Hygiene und Qualitätssicherung GmbH, Offenburg; ³ Indikator GmbH, Wuppertal

Berlin, 05. DEZ. 2024	 Sven Lehs Qualified Person/Sachkundige Person nach § 14 AMG
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