

	Freigabezertifikat - Master (DE)	Effective Date: 03 JUN 2024	
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RELEASE CERTIFICATE

Certificate of Analysis - Certificate of Compliance

Product: Medizinal Cannabisblüten Pedanos 24/1 LAC-CA
Batch: E142
Expiry date: 02/2025
Strength: Dronabinol (THC): approx. 24%
 Cannabidiol (CBD): < 1.0 %
Dosage Form: Dried Flowers
Destination: Germany
Package size: 10 grams


Manufacturer: Aurora Cannabis Enterprises Inc.
 Ridge - 4250 14th Avenue, Markham, Ontario, L3R 0J3, 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, 03. SEP. 2024		Qualified Person/Sachkundige Person nach § 14 AMG

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Product: Medizinal Cannabisblüten Pedanios 24/1 LAG-CA
Batch: E142
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Parameter	Method	Specification	Result
Characteristics	DAB Cannabis flos (Characteristics)	Characteristic smell	Complies
Identity¹			
<i>appearance</i>	DAB Cannabis flos (Identity A)	Comply with monograph	Complies
<i>microscopy</i>	DAB Cannabis flos (Identity B)	Comply with monograph	Complies
<i>thin layer chromatography</i>	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 %	9.2 %
Pesticides ^{*1}	Ph.Eur. 2.8.13	Comply with Ph.Eur. 2.8.13	Complies
Absence of heavy metals³			
<i>Lead</i>	Ph.Eur. 2.4.27	≤ 5 ppm	< 0.1 ppm
<i>Mercury</i>		≤ 0.1 ppm	< 0.05 ppm
<i>Cadmium</i>		≤ 1 ppm	< 0.05 ppm
Aflatoxins¹			
<i>Aflatoxin B1</i>	Ph.Eur. 2.8.18	≤ 2 ppb	< 0.5 ppb
<i>Sum of Aflatoxins B1, B2, G1, G2</i>		≤ 4 ppb	< 1.0 ppb
Microbiological purity²			
<i>Total aerobic microbial count (TAMC)</i>	Ph.Eur. 2.6.31	Comply with Ph.Eur. 5.1.8 B	
<i>Total yeast and molds count (TYMC)</i>		≤ 10 ⁴ cfu/g (max. 50 000 cfu/g)	< 10 000 cfu/g
<i>Bile-tolerant Gram-negative bacteria (BTGN)</i>		≤ 10 ² cfu/g (max. 500 cfu/g)	< 10 cfu/g
<i>E. coli</i>		≤ 10 ² cfu/g	< 10 cfu/g
<i>Salmonella</i>		Absent in 1 g	Absent in 1 g
		Absent in 25 g	Absent in 25 g
Related substance ¹ <i>Cannabinol (CBN)</i>	DAB Cannabis flos, Ph.Eur. 2.2.29	≤ 1.0 %	< 0.1 %
Assay¹			
<i>Dronabinol (THC)</i>	DAB Cannabis flos, Ph.Eur. 2.2.29	21.6 – 26.4 %	22,9 %
<i>Cannabidiol (CBD)</i>		< 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, 03. SEP. 2024	 Qualified Person/Sachkundige Person nach § 14 AMG
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