

Freigabezertifikat - Master (DE)

Doc ID: BER-QC-FORM-13

Effective Date: 03 JAN 2025

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RELEASE CERTIFICATE - Certificate of Analysis / Certificate of Compliance

Product:

Medizinal Cannabisblüten Pedanios 28/1 CMK-CA

Batch:

F024

Expiry date:

08/2025

Strength:

Total THC:

approx. 28 %

Total CBD:

≤ 1.0 %

Dosage Form: Destination:

Dried Flowers Germany

Package size:

10 grams Manufacturing date: 28.01.2025

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:

Storage:

Ph.Eur. Monograph <3028> "Cannabis flos" (current edition) Ph.Eur. Monograph <1433> "Herbal Drugs" (current edition)

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, 18.02.2025



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Product:

Medizinal Cannabisblüten Pedanios 28/1 CMK-CA

Batch: Expiry date: F024

08/2025

Parameter	Method	Specification	Result
Tested on bulk batch	·		
Identity ¹			
appearance	Ph.Eur. 3028, Identity A	Comply with monograph	Complies
microscopy	Ph.Eur. 3028 / 2.8.23, Identity B	Comply with monograph	Complies
High performance thin layer chromatography (HPTLC)	Ph.Eur. 3028 / 2.8.25, Identity C	Comply with monograph	Complies
Purity			
Foreign matter ¹	Ph.Eur. 3028 / 2.8.2	≤ 2 %	Complies
Seeds	7	Absent	Complies
Leaves		No leaves > 1.0 cm	Complies
Loss on Drying ¹	Ph.Eur. 3028 / 2.2.32	≤ 12.0 %	7.0 %
Pesticides*1	Ph.Eur. 2.8.13	Comply with Ph. Eur. 2.8.13	Complies
Absence of heavy metals ³	Ph.Eur. 3028 / 2.4.27		
Lead		≤ 0.5 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Cadmium		≤ 0.3 ppm	< 0.05 ppm
Arsenic	1	≤ 0.2 ppm	< 0.1 ppm
Aflatoxins ¹	Ph.Eur. 1433 / 2.8.18		
Aflatoxin B1		≤ 2 ppb	< 0.5 ppb
Sum of Aflatoxins B1, B2, G1, G2		≤ 4 ppb	< 1.0 ppb
Assay and Related Substances ¹ (Cannat	oinoids)		7/21
Total Tetrahydrocannabinol (THC)	Ph.Eur. 3028 / 2.2.29	25.2 - 30.8 %	29.7 %
Total Cannabidiol (CBD)	1	≤ 1.0 %	< 0.1 %
Total Cannabinol (CBN)		≤ 1.0 %	< 0.1 %
(Related substance)			
Tested on finished product			
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	< 10 000 cfu/g
Total yeast and molds count (TYMC)		≤10 ² cfu/g	< 10 cfu/g
Bile-tolerant Gram-negative bacteria		≤10 ² cfu/g	< 10 cfu/g
E. ∞li		Absent in 1 g	Absent in 1 g
Salmonella		Absent in 25 g	Absent in 25 g

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

Testing Sites:

Berlin, 18.02.2025	

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