

Freigabezertifikat - Master (DE) Effective Date: 03 JAN 2025

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RELEASE CERTIFICATE - Certificate of Analysis / Certificate of Compliance

Product:

Medizinal Cannabisblüten Pedanios 27/1 BLY-CA

Batch:

F032 08/2025

Expiry date: Strength:

Total THC:

approx. 27 % ≤ 1.0 %

Manufacturing date: 13.02.2025

Total CBD: Dried Flowers

Dosage Form: Destination: Package size:

Germany 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:

Ph.Eur. Monograph <3028> "Cannabis flos" (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, 27.02.2025

Sven Lehsing

Qualified Person according to EU-GMP



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Product:

Medizinal Cannabisblüten Pedanios 27/1 BLY-CA

Batch: Expiry date: F032

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		Absent	Complies	
Leaves		No leaves > 1.0 cm	Complies	
Loss on Drying ¹	Ph.Eur. 3028 / 2.2.32	≤ 12.0 %	8.3 %	
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		≤ 0.2 ppm	< 0.1 ppm	
Aflatoxins1 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 (Cannal	binoids)			
Total Tetrahydrocannabinol (THC)	Ph.Eur. 3028 / 2.2.29	24.3 - 29.7 %	29.0 %	
Total Cannabidiol (CBD)		≤ 1.0 %	< 0.1 %	
Total Cannabinol (CBN) (Related substance)		≤ 1.0 %	0.1 %	
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. coli		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:

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

Berlin, 27.02.2025		
	Sven Lehsing	
	Sven Lehsing Qualified Person according to EU-GMP	