

Freigabezertifikat - Master (DE)

Doc ID: BER-QC-FORM-13

Effective Date: 03 JAN 2025

Revision: 24

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## RELEASE CERTIFICATE - Certificate of Analysis / Certificate of Compliance

**Product:** 

Medizinal Cannabisblüten Pedanios 10/13 MBE-CA

Batch:

F209

Expiry date:

11/2025

Strength:

Total THC:

approx. 9.5 %

Total CBD: **Dried Flowers**  approx. 12.5 %

Dosage Form: Destination: Package size:

Germany 1000 grams Manufacturing date: 25.07.2025

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:

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, 30.07.2025

Dr. Michael Stöffler

Qualified Person according to EU-GMP



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**Product:** 

Medizinal Cannabisblüten Pedanios 10/13 MBE-CA

Batch:

F209

Expiry date: 11/2025

Parameter	Method	Specification	Result
Tested on bulk batch	-		
Identity <sup>1</sup>			
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 <sup>1</sup>	Ph.Eur. 3028 / 2.8.2	≤2%	Complies
Seeds		Absent	Complies
Leaves		No leaves > 1.0 cm	Complies
Loss on Drying <sup>1</sup>	Ph.Eur. 3028 / 2.2.32	≤ 12.0 %	7.7 %
Pesticides*1	Ph.Eur. 2.8.13	Comply with Ph. Eur. 2.8.13	Complies
Absence of heavy metals <sup>3</sup> 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
Aflatoxins <sup>1</sup> 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 <sup>1</sup> (Cannal	oinoids)	T-F	la l
Total Tetrahydrocannabinol (THC)	Ph.Eur. 3028 / 2.2.29	8.6 - 10.5 %	8.7 %
Total Cannabidiol (CBD)		11.3 - 13.8 %	12.6 %
Total Cannabinol (CBN)		≤ 1.0 %	< 0.1 %
(Related substance)			
Tested on finished product	-1-		
Microbiological purity <sup>2</sup>			
	Ph.Eur. 2.6.31	Comply with Ph.Eur. 5.1.8-B	
Total aerobic microbial count (TAMC)		≤10 <sup>4</sup> cfu/g	< 10 000 cfu/g
Total yeast and molds count (TYMC)		≤10 <sup>2</sup> cfu/g	< 10 cfu/g
Bile-tolerant Gram-negative bacteria		≤10 <sup>2</sup> cfu/g	< 10 cfu/g
E. coli		Absent in 1 g	Absent in 1 g
Salmonella		Absent in 25 g	Absent in 25 g

<sup>\*</sup> Batch-specific testing can be replaced by regular monitoring based on risk.

Berlin, 30.07.2025	Dr. Michael Stöffler Qualified Person according to EU-GMP

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