

Freigabezertifikat - Master (DE)

Effective Date: 03 JAN 2025

Doc ID: BER-QC-FORM-13

Revision: 24

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RELEASE CERTIFICATE - Certificate of Analysis / Certificate of Compliance

Product:

Medizinal Cannabisblüten Pedanios 10/13 MBE-CA

Batch:

E308

Expiry date:

07/2025

Strength:

Total THC:

approx. 9.5 % approx. 12.5 %

Dosage Form: Destination:

Total CBD: **Dried Flowers**

Package size:

Germany 10 grams Manufacturing date: 10.01.2025

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:

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.

3 1. JAN. 2025

Sven Lehsing

Qualified Person according to EU-GMP



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Product:

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Batch:

E308

Expiry date: 07/2025

Parameter	Method	Specification	Result
Tested on bulk batch			1.100011
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 %	7.4 %
Pesticides*1	Ph.Eur. 2.8.13	Comply with Ph. Eur. 2.8.13	
Absence of heavy metals ³	Ph.Eur. 3028 / 2.4.27		Compiles
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 ¹ Ph.Eur. 1433 / 2.8.18			· o.i ppiii
Aflatoxin B1		≤ 2 ppb	< 0.5 ppb
Sum of Aflatoxins B1, B2, G1, G2		≤ 4 ppb	< 1.0 ppb
Assay and Related Substances (Cannal	oinoids)	1 - 1 - 1	11.0 ppb
Total Tetrahydrocannabinol (THC)	Ph.Eur. 3028 / 2.2.29	8.6 - 10.5 %	9.1 %
Total Cannabidiol (CBD)		11.3 - 13.8 %	12.1 %
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 cfu/q
Bile-tolerant Gram-negative bacteria		V	< 10 cfu/g
E. coli			Absent in 1 g
Salmonella		~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	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

Sven Lehsing	
	Sven Lehsing Qualified Person according to EU-GMP