

	Freigabezertifikat - Master (CZ)	Effective Date: 03 JUN 2024	
	Doc ID: BER-QC-FORM-12	Revision: 22	Page: 1 of 2

## RELEASE CERTIFICATE E140

### Certificate of Analysis - Certificate of Compliance

**Product:** Medizinal Cannabisblüten Pedanios 10/13 MBE-CA  
**Batch:** E140  
**Expiry date:** 02/2025  
**Strength:** Dronabinol (THC): approx. 9.5%  
Cannabidiol (CBD): approx. 12.5%  
**Dosage Form:** Dried Flowers  
**Package size:** 10 grams  
**Destination:** Czech Republic  
  
**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  
  
**Irradiation date:** 10.10.2023  
  
**Irradiation dose:** 10.0 kGy  
  
**Testing method:** DAB Monograph Cannabisblüten (current edition)  
Ph.Eur. Monograph <1433> Herbal Drugs (current edition)  
  
**Storage:** Tightly closed, protected from light, below 25 °C.  
  
**Conclusion:** Meets the requirements of Czech Decree 236/2015 Coll.

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, 02.10.2024

Sven Lehsing  
Qualified Person acc. EU-GMP



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**Certificate of Analysis - Certificate of Compliance**

Product: Medizinal Cannabisblüten Pedanios 10/13 MBE-CA  
Batch: E140  
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Parameter	Method	Specification	Result	Evaluation
<b>Identity<sup>1</sup></b>				
Macroscopic description	Visual	Whole or fragmented, dried inflorescences of dark green, grey-green to brown-green colour, forming dense panicles. Small flowers are covered with bracts that are covered with glandular trichomes at the upper side.	Complies	Complies
Thin layer chromatography	Ph.Eur. 2.2.27	Visual evaluation	Complies	Complies
<b>Purity</b>				
Foreign material <sup>1</sup>	Ph.Eur. 2.8.2	≤ 2 %	Complies	Complies
Loss on Drying <sup>1</sup>	Ph.Eur. 2.2.32	≤ 10.0 %	7.9 %	Complies
Pesticides* <sup>1</sup>	Ph.Eur. 2.8.13	Comply with limits specified in Ph.Eur. 2.8.13	Complies	Complies
<b>Absence of heavy metals<sup>3</sup></b>				
Lead (Pb)	Ph.Eur. 2.4.27	≤ 5.0 µg/g (ppm)	< 0.1 ppm	Complies
Mercury (Hg)		≤ 0.1 µg/g (ppm)	< 0.05 ppm	Complies
Cadmium (Cd)		≤ 1.0 µg/g (ppm)	< 0.05 ppm	Complies
<b>Aflatoxins<sup>1</sup></b>				
Aflatoxin B1	Ph.Eur. 2.8.18	≤ 2 µg/kg (ppb)	< 0.5 ppb	Complies
Sum of Aflatoxins B1, B2, G1 and G2		≤ 4 µg/kg (ppb)	< 1.0 ppb	Complies
<b>Microbiological purity<sup>2</sup></b>				
Total aerobic microbial count (TAMC)	Ph.Eur. 2.6.12 and 2.6.13	≤ 10 <sup>3</sup> cfu/g	< 100 cfu/g	Complies
Total yeast and molds count (TYMC)		≤ 10 <sup>2</sup> cfu/g	< 10 cfu/g	Complies
Related substance <sup>1</sup> Cannabinol (CBN)	Ph.Eur. 2.2.29	≤ 1 %	< 0.1 %	Complies
<b>Assay<sup>1</sup></b>				
Dronabinol (THC)	Ph.Eur. 2.2.29	8.0 - 11.0 %	8.5 %	Complies
Cannabidiol (CBD)		11.0 - 14.0 %	12.4 %	Complies

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

Testing Sites:

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

Berlin, 02.10.2024	 Sven Lehning Qualified Person acc. EU-GMP
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