



Freigabezertifikat - Master (CZ)

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Effective Date: 07 Aug 2023

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RELEASE CERTIFICATE D043

Certificate of Analysis - Certificate of Compliance

Product: Medicinal Cannabis (flowers), Pedanios 8/8

Batch: D043

Expiry date: 04/2024

Strength: Dronabinol (THC): approx. 8 %
Cannabidiol (CBD): approx. 8 %

Dosage Form: Dried Flowers

Package size: 10 grams

Destination: Czech Republic

Manufacturer: Aurora Cannabis Enterprises Inc., 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: 12.04.2023

Irradiation dose: 10.6 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. Deviation 23-26 was evaluated and closed as uncritical.

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, 07.08.2023

Sven Lehsing
Qualified Person acc. EU-GMP

RELEASE CERTIFICATE D043

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Parameter	Method	Specification	Result	Evaluation
Identity¹				
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
Purity				
Foreign material ¹	Ph.Eur. 2.8.2	≤ 2 %	Complies	Complies
Loss on Drying ¹	Ph.Eur. 2.2.32	≤ 10.0 %	8.8 %	Complies
Pesticides* ¹	Ph.Eur. 2.8.13	Comply with limits specified in Ph.Eur. 2.8.13	Complies	Complies
Absence of heavy metals ³	Ph.Eur. 2.4.27			
Lead (Pb)		≤ 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
Aflatoxins ¹	Ph.Eur. 2.8.18			
Aflatoxin B1		≤ 2 µg/kg (ppb)	< 0.5 ppb	Complies
Sum of Aflatoxins B1, B2, G1 and G2		≤ 4 µg/kg (ppb)	< 1.0 ppb	Complies
Microbiological purity ²	Ph.Eur. 2.6.12 and 2.6.13	Comply with Ph.Eur. 5.1.4		
Total aerobic microbial count (TAMC)		≤ 10 ³ cfu/g	< 100 cfu/g	Complies
Total yeast and molds count (TYMC)		≤ 10 ² cfu/g	< 10 cfu/g	Complies
Related substance ¹ Cannabinol (CBN)	Ph.Eur. 2.2.29	≤ 1 %	< 0.1 %	Complies
Assay¹				
Dronabinol (THC)	Ph.Eur. 2.2.29	6.4 - 9.6 %	9.1 %	Complies
Cannabidiol (CBD)		6.4 - 9.6 %	9.4 %	Complies

* 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, 07.08.2023	 Sven Lehsing Qualified Person acc. EU-GMP
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