

RELEASE CERTIFICATE D006
Certificate of Analysis - Certificate of Compliance

Product: Medicinal Cannabis (flowers), Pedanios 8/8 DNK
Batch: D006
Expiry date: 11/2023
Strength: Dronabinol (THC): approx. 8 %
Cannabidiol (CBD): approx. 8 %
Dosage Form: Dried Flowers
Package size: 10 grams
Destination: Czech Republic

Manufacturer: Aurora Nordic Cannabis A/S, Denmark

Batch Release: AURORA Deutschland GmbH
Rudower Chaussee 29
D-12489 Berlin
GMP Certificate No.: DE_BE_01_GMP_2023_0012

Irradiation site: Sterigenics, Denmark

Irradiation date: 08.12.2022

Irradiation dose: 22.1 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, 15.03.2023

Sven Lehsing
Qualified Person acc. EU-GMP



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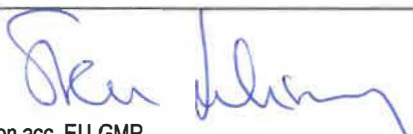
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Parameter	Method	Specification	Result	Evaluation
Identity¹				
Macroscopic description	Visual	Whole or fragmented, dried inflorescences of dark green, grey-green to brown-green colour, forming dense panicles. Small flowers are covered with bracts that are covered with glandular trichomes at the upper side.	Complies	Complies
Thin layer chromatography	ČL 2.2.27 (Ph.Eur. 2.2.27)	Visual evaluation	Complies	Complies
Purity				
Foreign material ¹	ČL 2.8.2 (Ph.Eur. 2.8.2)	≤ 2 %	Complies	Complies
Loss on Drying ¹	ČL 2.2.32 (Ph.Eur. 2.2.32)	≤ 10.0 %	9.2 %	Complies
Pesticides* ¹	ČL 2.8.13 (Ph.Eur. 2.8.13)	Comply with limits specified in ČL 2.8.13 (Ph.Eur. 2.8.13)	Complies	Complies
Absence of heavy metals³				
<i>Lead (Pb)</i>	ČL 2.4.27 (Ph.Eur. 2.4.27)	≤ 5.0 µg/g (ppm)	< 0.1 ppm	Complies
<i>Mercury (Hg)</i>		≤ 0.1 µg/g (ppm)	< 0.05 ppm	Complies
<i>Cadmium (Cd)</i>		≤ 1.0 µg/g (ppm)	< 0.05 ppm	Complies
Aflatoxins¹				
<i>Aflatoxin B1</i>	ČL 2.8.18 (Ph.Eur. 2.8.18)	≤ 2 µg/kg (ppb)	< 0.5 ppb	Complies
<i>Sum of Aflatoxins B1, B2, G1 and G2</i>		≤ 4 µg/kg (ppb)	< 1.0 ppb	Complies
Microbiological purity²				
<i>Total aerobic microbial count (TAMC)</i>	ČL 2.6.12 and 2.6.13 (Ph.Eur. 2.6.12 and 2.6.13)	≤ 10 ³ cfu/g	< 100 cfu/g	Complies
<i>Total yeast and molds count (TYMC)</i>		≤ 10 ² cfu/g	< 10 cfu/g	Complies
Related substance¹				
<i>Cannabinol (CBN)</i>	HPLC, ČL 2.2.29 (Ph.Eur. 2.2.29)	≤ 1 %	< 0.1 %	Complies
Assay¹				
<i>Dronabinol (THC)</i>	HPLC, ČL 2.2.29 (Ph.Eur. 2.2.29)	6.4 - 9.6 %	8.8 %	Complies
<i>Cannabidiol (CBD)</i>		6.4 - 9.6 %	8.9 %	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, 15.03.2023	 Sven Lehning Qualified Person acc. EU-GMP
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