

RELEASE CERTIFICATE C059**Certificate of Analysis - Certificate of Compliance****Product:** Medicinal Cannabis (flowers), Pedanios 8/8 DNK**Batch:** C059**Expiry date:** 04/2023**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
Wilmsdorfer Str. 98/99
D-10629 Berlin
GMP Certificate No.: DE_BE_01_GMP_2022_0024**Irradiation site:** Sterigenics, Denmark**Irradiation date:** 22.02.2022**Irradiation dose:** 21.5 kGy**Testing method:** DAB Monograph Cannabisblüten (current edition)
Ph.Eur. Monograph <1433> Herbal Drugs (current edition)**Testing sites:** Quality Services International GmbH
Flughafendamm 9a
D-28199 Bremen**Storage:** Tightly closed, protected from light, below 25 °C.**Remark:** We recommend the indication of the THC/CBD concentration "as it is" on the label of the bottle which is intended to be delivered to the patient.**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,

19. AUG. 2022

Qualified Person acc. EU-GMP


Dr. Michael Stöttner

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Product: Medicinal Cannabis (flowers), Pedanios 8/8 DNK
Batch: C059
Expiry date: 04/2023

Parameter	Method	Specification	Result	Evaluation
Identity				
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	ČL 2.8.2 (Ph.Eur. 2.8.2)	≤ 2 %	Complies	Complies
Loss on Drying	ČL 2.2.32 (Ph.Eur. 2.2.32)	≤ 10.0 %	8.1 %	Complies
Pesticides*	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 metals				
Lead (Pb)	ČL 2.4.27 (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
Aflatoxins				
Aflatoxin B1	ČL 2.8.18 (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
Microbiological purity				
Total aerobic microbial count (TAMC)	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
Total yeast and molds count (TYMC)		≤ 10 ² cfu/g	< 10 cfu/g	Complies
Related substance Cannabinol (CBN)	HPLC, ČL 2.2.29 (Ph.Eur. 2.2.29)	≤ 1 %	< 0.1 %	Complies
Assay				
Dronabinol (THC)	HPLC, ČL 2.2.29 (Ph.Eur. 2.2.29)	6.4 - 9.6 %	8.3 %	Complies
Cannabidiol (CBD)		6.4 - 9.6 %	8.1 %	Complies

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

Berlin, 19. AUG. 2022	 Qualified Person acc. EU-GMP Dr. Michael Stöffler
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