

RELEASE CERTIFICATE B090**Certificate of Analysis - Certificate of Compliance**

Product: Medicinal Cannabis (flowers), Pedanios 8/8 DNK
Batch: B090
Expiry date: 06/2022
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
Wilmersdorfer Str. 98/99
D-10629 Berlin
GMP Certificate No.: DE_BE_01_GMP_2021_0026

Irradiation site: Sterigenics, Denmark

Irradiation date: 01.06.2021

Irradiation dose: 21.2 – 21.8 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.

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, 11.10.2021

Dr. Michael Stöffler
Qualified Person acc. EU-GMP




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Parameter	Method	Specification	Results	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)	Max. 2 % (m/m)	Complies	Complies
Loss on Drying	ČL 2.2.32 (= Ph.Eur. 2.2.32)	Max. 10.0 %	8.7 %	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	ČL 2.4.27 (= Ph.Eur. 2.4.27)			
<i>Lead (Pb)</i>		Max. 5.0 µg/g (ppm)	< 0.1 ppm	Complies
<i>Mercury (Hg)</i>		Max. 0.1 µg/g (ppm)	< 0.05 ppm	Complies
<i>Cadmium (Cd)</i>		Max. 1.0 µg/g (ppm)	< 0.05 ppm	Complies
Aflatoxins	ČL 2.8.18 (= Ph.Eur. 2.8.18)			
<i>Aflatoxin B1</i>		Max. 2 µg/kg (ppb)	< 0.5 ppb	Complies
<i>Sum of Aflatoxins B1, B2, G1 and G2</i>		Max. 4 µg/kg (ppb)	< 1.0 ppb	Complies
Microbiological purity	ČL 2.6.12 and 2.6.13 (= Ph.Eur. 2.6.12 and 2.6.13)	Comply with Ph.Eur. 5.1.4		
<i>Total aerobic microbial count (TAMC)</i>		Max. 10 ³ cfu/g	< 100 cfu/g	Complies
<i>Total yeast and molds count (TYMC)</i>		Max. 10 ² cfu/g	< 10 cfu/g	Complies
Related substance	HPLC, ČL 2.2.29 (= Ph.Eur. 2.2.29)			
<i>Cannabinol (CBN)</i>		Max. 1 %	< 0.1 %	Complies
Assay				
<i>Dronabinol (THC)</i>	HPLC, ČL 2.2.29 (= Ph.Eur. 2.2.29)	8 % ± 20 % (6.4 – 9.6 %)	8.0 %	Complies
<i>Cannabidiol (CBD)</i>	HPLC, ČL 2.2.29 (= Ph.Eur. 2.2.29)	8 % ± 20 % (6.4 – 9.6 %)	7.9 %	Complies

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