

RELEASE CERTIFICATE C071**Certificate of Analysis - Certificate of Compliance**

Product: Medicinal Cannabis (flowers), Pedanios 8/8 DNK
Batch: C071
Expiry date: 06/2023
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: 10.05.2022

Irradiation dose: 21.4 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,

28. SEP. 2022


Sven Lehsing
Qualified Person acc. EU-GMP

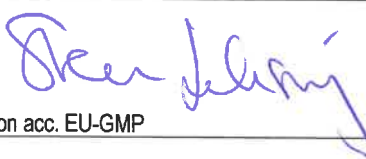
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| Parameter | Method | Specification | Result | Evaluation |
|--------------------------------------|---|---|-------------|------------|
| Identity | | | | |
| Macroscopic description | Visual | Whole or fragmented, dried inflorescences of dark green, 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) | Comply with Ph.Eur. 5.1.4 | | |
| Total yeast and molds count (TYMC) | | ≤ 10 ³ cfu/g | < 100 cfu/g | Complies |
| | | ≤ 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 % | 8.5 % | Complies |
| Cannabidiol (CBD) | | 6.4 - 9.6 % | 8.2 % | Complies |

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

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| Berlin, 28. SEP. 2022 |  Sven Lehsing Qualified Person acc. EU-GMP |
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