

RELEASE CERTIFICATE
Certificate of Analysis - Certificate of Compliance
(according to § 6 (3) ApBetrO)

Product: LOT 420 GLT
Batch no.: CLOT02A250240510
Expiry date: 01.2025
 Bulk batch no.: CLOT02R23008Z1B1
 Strength: Dronabinol (THC): 25.7 % Cannabidiol (CBD): < 0.1 %
 Dosage Form: Dried Flowers
 Package size: 250 grams
 Target country: Germany

Pharm. entrepreneur:
 Cantourage GmbH
 Feurigstr. 54
 10827 Berlin
 Germany
 GMP Certificate No.: DE_ST_01_GMP_2023_0048

Testing method: DAB Monograph "Cannabisblüten" (current edition) / Ph.Eur. Monograph <1433> "Herbal Drugs" (current edition)

No. of Analysis: PA 175/2024; PA 225/2024

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	Method	Specification	Result
Characteristics ¹⁾	DAB Cannabis flos (Characteristics)	Characteristic smell	Complies
Identity ¹⁾			
<i>appearance</i>	DAB Cannabis flos (Identity A)	Comply with monograph	Complies
<i>microscopy</i>	DAB Cannabis flos (Identity B)	Comply with monograph	Complies
<i>thin layer chromatography</i>	DAB Cannabis flos (Identity C), Ph.Eur. 2.2.27	Comply with monograph	Complies
Purity			
Foreign material ¹⁾	DAB Cannabis flos / Ph.Eur. 2.8.2	Max. 2 % (m/m)	Complies
Loss on Drying ¹⁾	DAB Cannabis flos / Ph.Eur. 2.2.32	Max. 10 %	8.2 %
Pesticides ¹⁾	Ph.Eur. 2.8.13	Comply with Ph.Eur. 2.8.13	Complies
Absence of heavy metals ³⁾	Ph.Eur. 2.4.27		
<i>Lead</i>		Max. 5.0 ppm	< 0.1 ppm
<i>Mercury</i>		Max. 0.1 ppm	< 0.05 ppm
<i>Cadmium</i>		Max. 1.0 ppm	< 0.05 ppm
Aflatoxin B1 ¹⁾	Ph.Eur. 2.8.18	≤ 2 ppb	< 0.5 ppb
Total Ash ¹⁾	Ph.Eur. 2.4.16	≤ 20 %	10.4 %

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	Method	Specification	Result
Microbiological purity ²⁾	Ph.Eur. 2.6.31	Comply with Ph.Eur. 5.1.8 C	
<i>Total aerobic microbial count (TAMC)</i>		Max. 500.000 cfu/gram	< 100.000 cfu/gram
<i>Total yeast and molds count (TYMC)</i>		Max. 50.000 cfu/gram	< 1.000 cfu/gram
<i>Bile-tolerant Gram negative bacteria</i>		≤ 10 ⁴ cfu/gram	< 100 cfu/gram
<i>E. coli</i>		Absent in 1 g	Absent in 1 g
<i>Salmonella</i>		Absent in 25 g	Absent in 25 g
Related substance ¹⁾ <i>Cannabinol (CBN)</i>	DAB Cannabis flos / Ph.Eur. 2.2.29	≤ 1.0 %	< 0.1 %
Assay ¹⁾			
<i>Dronabinol (THC)</i>	DAB Cannabis flos / Ph.Eur. 2.2.29	90.0 – 110.0 % of label claim	25.7 %
<i>Cannabidiol (CBD)</i>		≤ 1 %	< 0.1 %

Testing sites: 1) Quality Services International GmbH
Flughafendamm 9a
D-28199 Bremen

2) BAV-Institut für Hygiene und Qualitätssicherung GmbH
Hanns-Martin-Schleyer-Str. 25
D-77656 Offenburg

3) Indikator GmbH
Wilhelm-Muthmann-Str. 15
D-42329 Wuppertal

Storage: Tightly closed, protected from light, below 25 °C.

I hereby certify that all the manufacturing stages of this batch of drug product have been carried out in full compliance with the GMP requirements of the EU and with the specifications as stated in this document.

Lutherstadt Wittenberg, 28.05.2024



Constanze Pelzer
Qualified Person/Sachkundige Person nach § 14 AMG