

224 18657083

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

**Product:** Ceres No. 2  
**Batch no.:** CPTC02G0110000  
**Expiry date:** 01.2025  
**Bulk batch no.:** CPTC02BUL10001  
**Strength:** Dronabinol (THC): 27.1 % Cannabidiol (CBD): < 0.1 %  
**Dosage Form:** Dried Flowers  
**Package size:** 10 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 013/2024; PA 167/2024; PA 213/2024

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	Method	Specification	Result
Characteristics <sup>1)</sup>	DAB Cannabis flos (Characteristics)	Characteristic smell	Complies
Identity <sup>1)</sup>			
<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 <sup>1)</sup>	DAB Cannabis flos / Ph.Eur. 2.8.2	Max. 2 % (m/m)	Complies
Loss on Drying <sup>1)</sup>	DAB Cannabis flos / Ph.Eur. 2.2.32	Max. 10 %	8.5 %
Pesticides <sup>1)</sup>	Ph.Eur. 2.8.13	Comply with Ph.Eur. 2.8.13	Complies
Absence of heavy metals <sup>3)</sup>			
<i>Lead</i>	Ph.Eur. 2.4.27	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 B <sup>1)</sup>	Ph.Eur. 2.8.18	≤ 2 ppb	< 0.5 ppb
Total Ash <sup>1)</sup>	Ph.Eur. 2.4.16	≤ 20 %	10.1 %

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	Method	Specification	Result
Microbiological purity <sup>2)</sup>	Ph.Eur. 2.6.31	Comply with Ph.Eur. 5.1.8 C	
Total aerobic microbial count (TAMC)		Max. 500.000 cfu/gram	< 100.000 cfu/gram
Total yeast and molds count (TYMC)		Max. 50.000 cfu/gram	< 1.000 cfu/gram
Bile-tolerant Gram negative bacteria		≤ 10 <sup>4</sup> 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 <sup>1)</sup> Cannabinol (CBN)	DAB Cannabis flos / Ph.Eur. 2.2.29	≤ 1.0 %	< 0.1 %
Assay <sup>1)</sup>			
Dronabinol (THC)	DAB Cannabis flos / Ph.Eur. 2.2.29	90.0 – 110.0 % of label claim	27.1 %
Cannabidiol (CBD)		≤ 1 %	< 0.1 %

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

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

<sup>3)</sup> 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, 13.05.2024	 Constanze Pelzer Qualified Person/Sachkundige Person nach § 14 AMG