

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

Product: CAN Hydro PPC
Batch no.: CABK01G2510000
Expiry date: 03.2025
Bulk batch no.: CABK01BUL10000
Strength: Dronabinol (THC): 24.6 % Cannabidiol (CBD): < 0.1 %
Dosage Form: Dried Flowers
Package size: 250 grams
Target country: United Kingdom

Pharm. entrepreneur:

Cantourage GmbH

Feurigstraße 54

10827 Berlin

Germany

GMP Certificate No.: DE_ST_01_GMP_2023_0048

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

No. of Analysis: PA 160/2024; PA 291/2024

Page 1/2

	Method	Specification	Result
Identity ¹⁾			
<i>appearance</i>	Ph. Eur. Cannabis Flower (Identity A)	Comply with monograph	Complies
<i>microscopy</i>	Ph. Eur. Cannabis Flower (Identity B)	Comply with monograph	Complies
<i>HPTLC</i>	Ph. Eur. Cannabis Flower (Identity C), Ph. Eur. 2.8.25	Comply with monograph	Complies
Purity			
Foreign material ¹⁾	Ph. Eur. Cannabis Flower / Ph. Eur. 2.8.2	Max. 2 % (m/m); No seeds; No leaves > 1.0 cm	Complies
Loss on Drying ¹⁾	Ph. Eur. Cannabis Flower / Ph. Eur. 2.2.32	Max. 12.0 %	8.4 %
Pesticides ¹⁾	Ph. Eur. 2.8.13	Comply with Ph. Eur. 2.8.13	Complies
Absence of heavy metals ³⁾	Ph. Eur. Cannabis Flower / Ph. Eur. 2.4.27		
<i>Lead</i>		Max. 0.5 ppm	< 0.1 ppm
<i>Mercury</i>		Max. 0.1 ppm	< 0.05 ppm
<i>Cadmium</i>		Max. 0.3 ppm	< 0.05 ppm
<i>Arsenic</i>		Max. 0.2 ppm	< 0.1 ppm
Aflatoxin B1 ¹⁾	Ph. Eur. 2.8.18	≤ 2 ppb	< 0.5 ppb
Total Ash ¹⁾	Ph. Eur. 2.4.16	≤ 20 %	10.0 %

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Page 2/2

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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	< 10.000 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>	Ph. Eur. Cannabis Flower / Ph. Eur. 2.2.29	≤ 1.0 %	0.1 %
Assay ¹⁾			
<i>Dronabinol (THC)</i>	Ph. Eur. Cannabis Flower / Ph. Eur. 2.2.29	90.0 – 110.0 % of label claim	24.6 %
<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, 12.07.2024



Constanze Pelzer
Qualified Person/Sachkundige Person nach § 14 AMG