

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

Product: IQANNA No. 10
Batch no.: CCLL03A500220915
Expiry date: 03.2023
Bulk batch no.: CCLL03R22006B010
Strength: Dronabinol (THC): 25.2 % Cannabidiol (CBD): < 0.1 %
Dosage Form: Dried Flowers
Package size: 500 grams
Target country: Germany

Pharm. entrepreneur:
Cantourage GmbH
Feurigstraße 54
10827 Berlin
Germany
GMP Certificate No.: DE_ST_01_GMP_2022_0051

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

No. of Analysis: PA 140/2022

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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 %	10 %
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 %	8.5 %

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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	< 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/grams
<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	25.2 %
<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, 28.09.2022	 Constanze Pelzer Qualified Person/Sachkundige Person nach § 14 AMG