

CODE: FORM-DE- QA-010-31		BATCH CERTIFICATE Certificate of Analysis & Certificate of Compliance Canopy AKH 22 (Czech Republic)	Version:	01
			Active from:	01.03.2022

Product name: Canopy AKH 22
Batch number: AKH2311001-1R2-6
Potency: > 21 % THC, < 1 % CBD
Dosage form: Dried Cannabis flowers
Package size: 15g jars
CoCCZ: COCCZ2023019

Batch size: 9.839 kg
Manufacturing date: 21.07.2023
Destination country: Czech Republic
 Canopy Growth Germany GmbH
 Lanzstrasse 20
 D-68789 St. Leon-Rot
 Germany
Pharmaceutical Manufacturer (EU GMP): GMP certificate number: DE_BW_01_GMP_2021_0088

Pharmaceutical Manufacturer and grower (EU GMP and GACP): Tweed Inc.
 1 Hershey Drive
 Smiths Falls, On, Kanada
 K7A OA8
 GMP certificate number: DE_BW_01_GMP_2023_0007

Certificate of Analysis (CoA)

Parameters (References)	Specifications	Result	Evaluation
Identification			
Identity macroscopic (DAB-Monography Identity A)	Complies with DAB (DAB-Monography)	conforms	passed ²⁾
Identity microscopic (DAB-Monography Identity B)	Complies with DAB (DAB-Monography)	conforms	passed ²⁾
TLC (DAB-Monography Identity C)	Complies with DAB (DAB-Monography)	conforms	passed ²⁾
Assay			
HPLC (DAB-Monography)	Total Δ^9 -THC: > 21 w/w Total CBD: < 1 % w/w (DAB-Monography)	23.4 % w/w 0.19 % w/w	passed ²⁾
Purity test			
Related substances (DAB-Monography)	CBN $\leq$ 1 % w/w (DAB-Monography)	0.03 % w/w	passed ²⁾
Microbiological purity (Ph. Eur. 2.6.12, 2.6.13, 2.6.31, 5.1.4 Inhala, 5.1.8 Table B), Ph. Cz. 2.6.12, 2.6.13)	TAMC: $\leq 10^2$ (≤ 200) CFU/g (Ph. Eur. 5.1.4) TYMC: $\leq 10^1$ (≤ 20) CFU/g (Ph. Eur. 5.1.4) Bile Tolerant Gram neg bacteria: absent/g (Ph. Eur. 5.1.4) P. aeruginosa: absent/g (Ph. Eur. 5.1.4) S. aureus: absent/g (Ph. Eur. 5.1.4) Salmonella: absent/25g (Ph. Eur. 5.1.8 B) E. coli: absent/g (Ph. Eur. 5.1.8 B)	< 10 CFU/g < 10 CFU/g absent/g absent/g absent/g absent/25g absent/g	passed ²⁾
Foreign matters (Ph. Eur. 2.8.2, Ph. Cz. 2.8.2 01/22012 herbal drugs)	≤ 2 % (DAB-Monography)	0 %	passed ¹⁾
Pesticides (Ph. Eur. + Ph. Cz. 2.8.13)	absent (Ph. Eur. Plantae medicinales)	conforms	passed ²⁾

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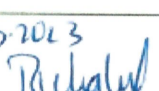
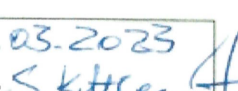
Certificate of Analysis (CoA)

Parameters (References)	Specifications	Result	Evaluation
Gamma-Irradiation (Irradiation source Cobalt 60)	≤ 10 kGy	8.9 kGy	passed ¹⁾
Heavy metals (Ph. Eur. + Ph. Cz. 2.4.27, Ph. Eur. Herbal Drugs 01/1012: 1433)	As: ≤ 1.0 ppm Cd: ≤ 1.0 ppm (Ph. Eur. Plantae medicinales) Pb: ≤ 5.0 ppm (Ph. Eur. Plantae medicinales) Hg: ≤ 0.1 ppm (Ph. Eur. Plantae medicinales)	< 0.1004 ppm < 0.1004 ppm < 0.0998 ppm < 0.0500 ppm	passed ¹⁾
Total ash (Ph. Eur. + Ph. Cz. 2.4.16)	< 20 % (w/w)	9.99 %	passed ¹⁾
Loss on drying (Ph. Eur. + Ph. Cz. 2.2.32)	≤ 10 % w/w (DAB-Monography)	6.47 %	passed ²⁾
Aflatoxins (Ph. Eur. + Ph. Cz. 2.8.18)	Total B1+B2+G1+G2 ≤ 4 ppb B1 ≤ 2 ppb (Ph. Eur. 2.8.18)	not detected not detected	passed ²⁾
Ochratoxin A (Ph. Eur. + Ph. Cz. 2.8.22)	< 20 µg/kg	not detected	passed ¹⁾
Shelf life			
Expiry date	Label result	12/2023	passed ²⁾

Laboratories		
Tweed/Experchem Canada ¹⁾	Number of analysis / date:	ABC26113 / 05.04.2023
	Number of analysis / date:	ABC29324 / 06.04.2023
	Number of analysis / date:	308101 / 22.03.2023
Labor Wessling, Germany ²⁾	Number of analysis / date:	CMS23-008958-1 / 23.05.2023
	Number of analysis / date:	CMS23-011406-1 / 03.07.2023

Certificate of Compliance (CoC)

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.	
25.07.2023 	
Date, Signature Dr. Antonella Cellini-Wagner Qualified Person §14 AMG	Contact: antonella.cellini@canopygrowth.com

Erstellt: 01.03.2023 Alevtina Kaa 	Geprüft: 01.03.2023 Dr. Richa Garg 	Freigegeben: 01.03.2023 Dr. Stefan Kettelhoit 
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