

Certificate of Analysis

Cannabidiol DAC-Quality / API

Product	Cannabidiol DAC-Quality / API		
CoA-No	AZ22-44-001.1	Specification Number	SPE 194
Article-Number	22-0022	Batch-Number	-
Manufacturing Date	19/11/2022	Batch-Number Bulk	22-44-001.1
Packaging Date	-	Container / amount	Airtight, light-protected vessel
Retest Date	18/11/2023	Storage Condition	15 - 25 °C, airtight, dark

Test parameter	Method	Specification	Result
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Characteristics			
Appearance	Visual control	White to yellow powder	Complies

Identity			
Infrared spectroscopy	Ph. Eur. 2.2.24 (IR)	Must correspond to reference spectrum of Cannabidiol	Complies (R ² =99.3 %)

Purity and physical parameters

Related substances			
CBD-C3	Ph. Eur. 2.2.29 (HPLC)	n.a.	0.16 % (m/m)
CBD-C4		n.a.	0.22 % (m/m)

Unspecified impurities			
Unspecified impurities	Ph. Eur. 2.2.29 (HPLC)	Unspecified impurities* each ≤ 0.10 % (m/m)	n.d.
Sum of all impurities (rel. subst. inclusive)		Sum of all impurities* ≤ 0.5 % (m/m)	0.4 % (m/m)

Physical parameters			
Specific rotation	Ph. Eur. 2.2.7 (Polarimetry)	-129.5 to -135.0	-130.1
Sulfate ash	Ph. Eur. 2.4.14	≤ 0.1 % (m/m)	0.0 % (m/m)**
Water content	Ph. Eur. 2.5.12	< 0.1 % (m/m)	0.0 % (m/m)

*Disregard limit for impurities = 0.05 %

**Value taken from AZ20_44_001.1

Content			
CBD-C5	Ph. Eur. 2.2.29 (HPLC)	98.0 to 102.0 % (m/m)	99.0 % (m/m)

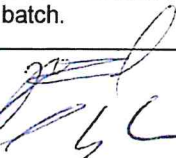
I hereby certify that the above information is authentic and accurate.

This batch has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the EU-GMP requirements of the local Regulatory Authority.

Except for the validation / verification of the compendial analytical method implemented for the purity testing.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.

This certificate is only valid for closed containers of this specific batch.

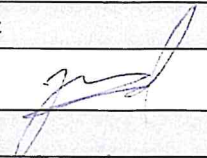
Author:	Name: J. Espel	Signature: 	Date: 01/12/2022
Approved by QP:	Name: U. Lengweiler	Signature: 	Date: 01.12.2022

1. Spezifikationsblatt Nr.	194	1.1 Spezifikationsart	Freigabespezifikation ☒ Laufzeitspezifikation ☐
2. Stammdaten			
2.1. Artikelbezeichnung	Cannabidiol (CBD) – DAC Qualität / API		
2.2. Lieferant	---	2.3. Lieferanten Artikelnummer	---
2.4. Artikelnummer Schibano Pharma AG	Bulk: 22-0022 Endprodukt: 31-0022		
2.5. Verwendungszweck	Wirkstoff (API)		
2.6. Packungseinheit	Luftdichter, lichtundurchlässiger Behälter in geeigneter Grösse aus Glas, Kunststoff oder Edelstahl		
2.7. Hersteller	Schibano Pharma AG		
3. Zusammensetzung / Qualitätsmerkmale			
Parameter	Spezifikation	Prüfvorschrift	Methode
3.1 Beschreibung			
Aussehen	Weiss – gelbliches Pulver	----	Visuell
3.2 Identität			
IR-Spektroskopie	Korrelationskoeffizient mit Referenzspektrum muss über 95% liegen	PVS 020	Ph.Eur. 2.2.24
3.3 Physikalische Parameter und Reinheit			
Nicht spezifizierte Verunreinigungen CBN, Δ ⁹ -THC und Δ ⁸ -THC CBD-C3 und CBD-C4 Summe aller Verunreinigungen	je ≤ 0.10 % je ≤ 0.10 % n.a. ≤ 0.5 %	PVS 020	Ph.Eur. 2.2.29 (HPLC)
Spezifische Drehung	-129.5 bis -135.0	PVS 020	Ph.Eur. 2.2.7
Sulfatasche	≤ 0.1 %	PVS 020	Ph.Eur. 2.4.14
Restlösemittel Ethanol n-Heptan	≤ 0.25 % ≤ 0.25 %	PVS 042 PVS 043	Ph. Eur. 2.2.28
Wasser	< 0.1 %	PVS 022	Ph. Eur. 2.5.12
Pestizide	Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 2.8.13 angegebenen Grenzwerten entsprechen.	Extern	GC-MS/MS, LC-MS/MS
Aflatoxin Aflatoxin B1 Summe Aflatoxine B1, B2, G1, G2	< 2 µg/kg < 4 µg/kg Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 2.8.18 angegebenen Grenzwerten entsprechen.	Extern	HPLC-FLD
Schwermetalle Blei Pb Cadmium Cd Quecksilber Hg	≤ 5.0 mg/kg ≤ 1.0 mg/kg ≤ 0.1 mg/kg Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 1433 angegebenen Grenzwerten entsprechen.	Extern	Ph.Eur. 2.4.27
Mikrobiologie TAMC TYMC Escherichia coli Salmonellen	< 10 ⁷ KBE/g * < 10 ⁵ KBE/g * < 10 ³ KBE/g nicht nachweisbar in 25 g Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 5.1.8(A) angegebenen Grenzwerten entsprechen.	Extern Extern Extern Extern	Ph. Eur. 2.6.12 Ph. Eur. 2.6.12 Ph. Eur. 2.6.31 Ph. Eur. 2.6.31

* Maximale akzeptierbare Anzahl gemäss Ph. Eur. ist die jeweilige Spezifikation x 5.

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3.4 Gehalt			
CBD	98.0 % - 102.0 %	PVS 020	Ph.Eur. 2.2.29 (HPLC)

4. Lagerungs- und Transportbedingungen / Sicherheitshinweise		
Parameter	Sollwerte	Bemerkung
Temperatur	15 – 25 °C	Dunkel lagern
5. Haltbarkeit / Retest-Datum		
Bulk: 1 Jahr nach Herstellungsdatum* (minus 1 Tag)		*Herstellungsdatum entspricht dem Datum des Trocknens der Kristalle
Endprodukt: 1 Jahr nach Abfüllung (minus 1 Tag)		
6. Unterschriften		
Ersteller: QK	Datum	Unterschrift
J. Espel	06.11.2023	
Prüfung & Genehmigung: FvP	Datum	Unterschrift
U. Lengweiler	06.11.2023	

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier	Product Name: Cannabidiol CAS-No.: 13956-29-1
1.2. Relevant identified uses of the substance or mixture and uses advised against	Laboratory chemical. Manufacture of materials.
1.3. Details of the supplier of the safety data sheet	Schibano Pharma AG Tüfi 450 CH-9105 Wald-Schönengrund +41 (0)79 300 03 69 info@schibano-pharma.ch
1.4. Emergency telephone number	+41 (0)79 300 03 69 (Schibano Pharma) Mon-Fri 8:00-18:30

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture	Acute oral toxicity: Category 4 Reproductive toxicity: Category 2 Aquatic chronic toxicity: Category 4
2.2. Label elements	 GHS Signal word: Warning GHS Hazard statements: H301: Harmful if swallowed H361: Suspected of damaging fertility or the unborn child H413: May cause long lasting harmful effects to aquatic life GHS Precautionary statements: Prevention P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves. Response P301+312+330: IF SWALLOWED: Call a POISON CENTER or a physician and rinse mouth, if you feel unwell. P308+313: IF exposed or concerned: Get medical advice. Disposal P501: Dispose of content in accordance with national and local regulations.

2.3. Other hazards	Effects and Symptoms: May be harmful by inhalation. May cause drowsiness or dizziness. May affect the inflammatory response. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.
SECTION 3: Composition/information on ingredients	
3.1. Substances	Common name: Cannabidiol Other names: CBD CAS-No: 13956-29-1 RTECS: VH1600000 Impurities: not specified
3.2. Mixtures	Not applicable.
SECTION 4: First aid measures	
4.1. Description of first aid measures	If inhaled: Move the person into fresh air. If not breathing, give artificial respiration and get immediate medical attention. In case of skin contact: Wash off with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse. In case of eye contact: Hold eyelids apart and flush eyes with water. Have eyes examined and tested by medical personnel if any irritation occurs. If swallowed: Rinse mouth with water, provided the person is conscious. Never give anything by mouth to an unconscious person. Get medical attention if exposed to a great amount. Do NOT induce vomiting unless directed to do so by medical personnel.
4.2. Most important symptoms and effects, both acute and delayed	Drowsiness or wakefulness. May affect the inflammatory response. If swallowed, the symptoms may occur one or more hours later.
4.3. Indication of any immediate medical attention and special treatment needed	Treat symptoms. No special immediate treatment required.
SECTION 5: Firefighting measures	
5.1. Extinguishing media	Use water spray, alcohol-resistant foam, carbon dioxide or dry chemical spray. A solid water stream may be inefficient.
5.2. Special hazards arising from the substance or mixture	May produce carbon oxides on combustion.
5.3. Advice for firefighters	Keep containers cool with water spray. If necessary, wear self-contained breathing apparatus and full protective gear.

SECTION 6: Accidental release measure

6.1. Personal precautions, protective equipment and emergency procedures	Wear gloves and other appropriate personal protection.
6.2. Environmental precautions	Avoid release into the environment or drains.
6.3. Methods and material for containment and cleaning up	Use an appropriate solvent in safety condition or soap to collect the spill.
6.4. Reference to other sections	Not applicable.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid excessive exposure.
7.2. Conditions for safe storage, including any incompatibilities	Keep protected from light and air at 15 – 25 °C. Avoid exposition to strong oxidizing agents.
7.3. Specific end use(s)	No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	No data available.
8.2. Exposure controls	Use process enclosures, local exhaust ventilation and general industrial hygiene practice.
8.3. Individual protection measures	Eye protection: Safety glasses. Skin protection: Lab coat and protective gloves. Wash thoroughly with soap if contact occurs. Respiratory protection: No specific requirements. Thermal hazard: No specific requirements.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties	Appearance: white to slightly yellow solid Odour: none pH: no data available Melting point: 62 °C – 65 °C Boiling point: 463.9±45.0 °C at 1 atm Flash point: 206.3±23.3 °C Evaporation rate: no data available Flammability: no data available Explosive limits: LEL: no data. UEL: no data Vapor pressure: 0±1.2 mmHg at 25 °C Vapor density: no data available Relative density: no data available Solubility: poor water soluble ~36 mg/ml in Ethanol, DMSO, DMF ~250 µg/ml in 1:3 DMSO/PBS (pH 7.2) Partition coefficient: 1,26 x 10⁶ – 2,14 x 10⁶ (oct/wat) Autoignition point: no data available Decomposition temp.: no data available Viscosity: no data available
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9.2. Other information	Density: 1.025 g/cm ³ Molecular formula: C ₂₁ H ₃₀ O ₂ Molecular weight: 314.46 g/mol Percent volatile: no data available																												
SECTION 10: Stability and reactivity																													
10.1. Reactivity	No data available.																												
10.2. Chemical stability	Stable at room temperature.																												
10.3. Possibility of hazardous reactions:	Polymerization will not occur.																												
10.4. Conditions to avoid	Light.																												
10.5. Incompatible materials	Strong oxidizing agents.																												
10.6. Hazardous decomposition products	No data available.																												
SECTION 11: Toxicological information																													
11.1. Information on toxicological effects	Acute toxicity <table><tr><td>LD₅₀ intravenous</td><td>mouse:</td><td>50 mg/kg</td></tr><tr><td></td><td>dog:</td><td>unknown, >254 mg/kg</td></tr><tr><td></td><td>monkey:</td><td>212 mg/kg</td></tr><tr><td>Lowest lethal dose oral</td><td>mouse:</td><td>unknown, >750 mg/kg</td></tr><tr><td></td><td>monkey:</td><td>unknown, >300 mg/kg</td></tr><tr><td>Lowest toxic dose oral</td><td>human:</td><td>unknown, >20 mg/kg</td></tr></table> Skin corrosion or irritation: Not classified as hazardous. Serious eye damage or irritation: Not classified as hazardous. Respiratory or skin sensitization: Not classified as hazardous. Germ cell mutagenicity: No data available. Carcinogenicity: No component of the product at levels ≥0.1% is identified as probable, possible, or confirmed human carcinogen by IARC. Reproductive toxicity: Suspected to damage fertility or the unborn child. <table><tr><td>TDLo oral</td><td>mouse female:</td><td>50 mg/kg</td></tr><tr><td>TDLo oral</td><td>mouse male:</td><td>750 mg/kg</td></tr></table> Specific target organ toxicity <table><tr><td>Single exposure:</td><td>Not classified as hazardous.</td></tr><tr><td>Repeated exposure:</td><td>Not classified as hazardous.</td></tr></table> Aspiration hazard: Not classified as hazardous.	LD ₅₀ intravenous	mouse:	50 mg/kg		dog:	unknown, >254 mg/kg		monkey:	212 mg/kg	Lowest lethal dose oral	mouse:	unknown, >750 mg/kg		monkey:	unknown, >300 mg/kg	Lowest toxic dose oral	human:	unknown, >20 mg/kg	TDLo oral	mouse female:	50 mg/kg	TDLo oral	mouse male:	750 mg/kg	Single exposure:	Not classified as hazardous.	Repeated exposure:	Not classified as hazardous.
LD ₅₀ intravenous	mouse:	50 mg/kg																											
	dog:	unknown, >254 mg/kg																											
	monkey:	212 mg/kg																											
Lowest lethal dose oral	mouse:	unknown, >750 mg/kg																											
	monkey:	unknown, >300 mg/kg																											
Lowest toxic dose oral	human:	unknown, >20 mg/kg																											
TDLo oral	mouse female:	50 mg/kg																											
TDLo oral	mouse male:	750 mg/kg																											
Single exposure:	Not classified as hazardous.																												
Repeated exposure:	Not classified as hazardous.																												

11.2. Routes of exposure	Ingestion: May affect mucosal inflammatory response. Inhalation: May affect mucosal inflammatory response. Skin: May affect skin inflammatory response. Eyes: May affect eye inflammatory response.
11.3. Symptoms of exposure	Exposure may affect the inflammatory response and cause dizziness or wakefulness. To the best of our knowledge, the toxicological properties have not been fully investigated.
11.4. Delayed and immediate effects	No data available.
SECTION 12: Ecological information	
12.1. Toxicity	No data available.
12.2. Persistence and degradability	No data available
12.3. Bioaccumulative potential	Poor water soluble. High partition coefficient.
12.4. Mobility in soil	Poor water soluble. High partition coefficient.
12.5. Results of PBT and vPvB assessment	No data available.
12.6. Other adverse effects	No data available.
SECTION 13: Disposal considerations	
13.1. Waste treatment methods	Dispose in accordance with local, state, and federal regulations. Refer to information in section 8 for exposure control.
SECTION 14: Transport information	
14.1. UN number	-
14.2. UN proper shipping name	Not classified as hazardous for transport by ARD/RID, IMDG and IATA.
14.3. Transport hazard class(es)	Not classified as hazardous for transport.
14.4. Packing group	-
14.5. Environmental hazards	The product is not classified as environmentally hazardous according to the UN Model Regulations, ARD, RID, and AND; nor as a marine pollutant according to the IMDG Code.
14.6. Special precautions for user	No data available.
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	No data available.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Restricted substance in Slovakia according to the law n.43/2011.

15.2. Chemical safety assessment

A chemical safety assessment has not been made for this product.

SECTION 16: Other information

This SDS was prepared in accordance with Regulation (EC) No. 1272/2008.

This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.