

Certificate of Analysis

Δ^9 -Tetrahydrocannabinol DAC-Quality / API

Product	Δ^9 -Tetrahydrocannabinol DAC-Quality / API		
CoA-No	AZ22-49-001	Specification Number	SPE 419
Article-Number	23-0020	Batch-Number	-
Manufacturing Date	10/12/2022	Batch-Number Bulk	22-49-001
Packaging Date	-	Container / amount	Airtight, light-protected vessel
Retest Date	09/06/2023	Storage Condition	2 - 8 °C, airtight, dark

Test parameter	Method	Specification	Result
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Characteristics			
Appearance	Visual control	Almost colorless to light yellow, sometimes faint purple on the surface, oily liquid or resinous mass	Complies

Identity			
Infrared spectroscopy	Ph. Eur. 2.2.24 (IR)	Must correspond to reference spectrum	Complies

Purity and physical parameters			
Related substances			
CBN	Ph. Eur. 2.2.29 (HPLC)	$\leq 1.0 \text{ } (\text{m/m})$	0.1 % (m/m)
Δ^8 -THC		$\leq 2.0 \text{ } (\text{m/m})$	0.2 % (m/m)

Impurities			
Other impurities	Ph. Eur. 2.2.29 (HPLC)	Each $\leq 0.10 \text{ } (\text{m/m})$	n.d.
Sum of all impurities (rel. subst. inclusive except Δ^8 -THC)		Sum of all impurities* $\leq 3.0 \text{ } (\text{m/m})$	0.1 % (m/m)

Residual solvents			
Ethanol	Ph. Eur. 2.2.28 (GC)	$\leq 0.5 \text{ } (\text{m/m})$	< 0.5 % (m/m)

Physical parameters			
Water content	Ph. Eur. 2.5.12	< 0.2 % (m/m)	< 0.1 % (m/m)

*Disregard limit for impurities = 0.05 %

Content			
Δ^9 -THC	Ph. Eur. 2.2.29 (HPLC)	95.0 to 100.0 % (m/m)	99.6 % (m/m)

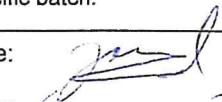
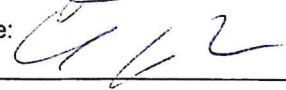
I hereby certify that the above information is authentic and accurate.

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.

All implemented analytical methods were properly validated / verified except for the methods implemented for the purity testing of the biomass.

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

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

Author:	Name: J. Espel	Signature: 	Date: 17/12/2022
Approved by QP:	Name: U. Lengweiler	Signature: 	Date: 17.12.2022

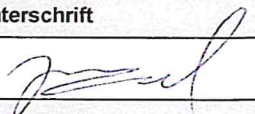
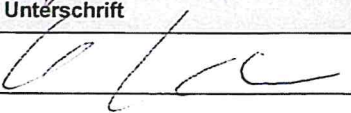
	Spezifikation Δ^9 -Tetrahydrocannabinol (THC) – DAC-Qualität / API		SPE 419_03 Revision: nach Bedarf Seite: 1 von 2 Gültig ab: 06.11.2023
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1. Spezifikationsblatt Nr.	419	1.1 Spezifikationsart	Freigabespezifikation ☒ Laufzeitspezifikation ☐
2. Stammdaten			
2.1. Artikelbezeichnung	Δ^9 -Tetrahydrocannabinol (THC) – DAC Qualität / API		
2.2. Lieferant	---	2.3. Lieferanten Artikelnummer	---
2.4. Artikelnummer Schibano Pharma AG	Bulk: 23-0020 Endprodukt: 33-0020		
2.5. Verwendungszweck	Wirkstoff (API)		
2.6. Packungseinheit	Luftdichter, lichtundurchlässiger Behälter in geeigneter Grösse aus Glas oder Edelstahl		
2.7. Hersteller	Schibano Pharma AG		
3. Zusammensetzung / Qualitätsmerkmale			
Parameter		Spezifikation	Prüfvorschrift Methode
3.1 Beschreibung			
Aussehen		Fast farblose bis hellgelbe, an der Oberfläche bisweilen blass violette, ölige Flüssigkeit oder harzartige Masse.	---- Visuell
3.2 Identität			
IR-Spektroskopie		Korrelationskoeffizient mit Referenzspektrum muss über 95% liegen.	PVS 050 Ph.Eur. 2.2.24
3.3 Physikalische Parameter und Reinheit			
Cannabinol (korrigierte Fläche)		$\leq 1.0 \%$	PVS 050 Ph.Eur. 2.2.29 (HPLC)
Δ^8 -Tetrahydrocannabinol		$\leq 2.0 \%$	
Jede weitere Verunreinigung		$\leq 1.0 \%$	
Summe aller Verunreinigungen (ausgenommen Δ^8 -Tetrahydrocannabinol)		$\leq 3.0 \%$	
Restlösemittel			
Ethanol		$\leq 0.5 \%$	PVS 047 Ph. Eur. 2.2.28
Wasser		$< 0.2 \%$	PVS 048 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		$< 2 \mu\text{g/kg}$	Extern HPLC-FLD
Summe Aflatoxine B1, B2, G1, G2		$< 4 \mu\text{g/kg}$	
		Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 2.8.18 angegebenen Grenzwerten entsprechen.	
Schwermetalle Blei Pb		$\leq 5.0 \text{ mg/kg}$	Extern Ph.Eur. 2.4.27
Cadmium Cd		$\leq 1.0 \text{ mg/kg}$	
Quecksilber Hg		$\leq 0.1 \text{ mg/kg}$	
		Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 1433 angegebenen Grenzwerten entsprechen.	
Mikrobiologie TAMC		$< 10^6 \text{ KBE/g}^*$	Extern Ph. Eur. 2.6.12 Extern Ph. Eur. 2.6.12 Extern Ph. Eur. 2.6.31 Extern Ph. Eur. 2.6.31
TYMC		$< 100^6 \text{ KBE/g}^*$	
Escherichia coli		$< 1000 \text{ KBE/g}$	
Salmonellen		nicht nachweisbar in 25 g	
		Wird in der Pflanze bestimmt. Muss den in Ph. Eur. 5.1.8(A) angegebenen Grenzwerten entsprechen.	

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

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3.4 Gehalt			
Δ^9 -Tetrahydrocannabinol	95.0 % - 100.0 %	PVS_050	Ph.Eur. 2.2.29 (HPLC)

4. Lagerungs- und Transportbedingungen / Sicherheitshinweise		
Parameter	Sollwerte	Bemerkung
Temperatur	2 - 8 °C	Dunkel lagern
5. Haltbarkeit / Retest-Datum		
6 Monate (minus 1 Tag)		
6. Unterschriften		
Ersteller: QM	Datum	Unterschrift
J. Espel	06.11.2023	
Prüfung & Genehmigung: Stv. FvP	Datum	Unterschrift
U. Lengweiler	06.11.2023	

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

1.1. Product identifier	Product Name: Δ^9 -Tetrahydrocannabinol CAS-No.: 1972-08-3
1.2. Relevant identified uses of the substance or mixture and uses advised against	Laboratory chemical.
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

2 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: H302: Toxic 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 P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P301+P312: If swallowed: call a poison center or doctor/physician if you feel unwell. P304+P340: If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P403+P233: Store in a well ventilated place. Keep container tightly closed. P405: Store locked up.

	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.
3 SECTION 3: Composition/information on ingredients	
3.1. Substances	Common name: THC Other names: Dronabinol, Tetrahydrocannabinol CAS-No: 1972-08-3 RTECS: HP8225000 Impurities: not specified
3.2. Mixtures	Not applicable.
4 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.
5 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.

6 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	Collect the spill mechanically.
6.4. Reference to other sections	Information for safe handling see section 7. Information for personal protection see section 8. Information for disposal see section 13

7 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.

8 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.

9 SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties	Appearance: Almost colorless to light yellow, sometimes faint purple on the surface or resinous mass. Odour: none pH: no data available Melting point: no data available Boiling point: 200 °C at 1 atm Flash point: no data available Evaporation rate: no data available Flammability: no data available Explosive limits: LEL: no data. UEL: no data Vapor pressure: no data available Vapor density: no data available Relative density: no data available Solubility: poor water soluble (0.0028 mg/mL at 23 °C) Partition coefficient: not water soluble Autoignition point: no data available
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	Decomposition temp.: no data available Viscosity: no data available
9.2. Other information	Density: no data available Molecular formula: $C_{21}H_{30}O_2$ Molecular weight: 314.46 g/mol Percent volatile: no data available
10 SECTION 10: Stability and reactivity	
10.1. Reactivity	No data available.
10.2. Chemical stability	Stable at room temperature. Oxidation may occur.
10.3. Possibility of hazardous reactions:	None.
10.4. Conditions to avoid	Light, heat.
10.5. Incompatible materials	Strong oxidizing agents.
10.6. Hazardous decomposition products	No data available.
11 SECTION 11: Toxicological information	
11.1. Information on toxicological effects	Acute toxicity LD₅₀ oral mouse: 482 mg/kg rat: 666 mg/kg dog: 3000 mg/kg monkey: 9000 mg/kg LD₅₀ intravenous mouse: 42 mg/kg rat: 29 mg/kg Lowest toxic dose oral human: unknown 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: Not confirmed human carcinogen. Reproductive toxicity: Suspected to damage fertility or the unborn child. TD_{Lo} oral mouse female: 110 mg/kg TD_{Lo} oral mouse male: 125 mg/kg Specific target organ toxicity Single exposure: Not classified as hazardous. Repeated exposure: Not classified as hazardous. Aspiration hazard: 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 on humans.
11.4. Delayed and immediate effects	No data available.
12 SECTION 12: Ecological information	
12.1. Toxicity	No data available.
12.2. Persistence and degradability	No data available
12.3. Bioaccumulative potential	Not water soluble.
12.4. Mobility in soil	Not water soluble.
12.5. Results of PBT and vPvB assessment	No data available.
12.6. Other adverse effects	No data available.
13 SECTION 13: Disposal considerations	
13.1. Waste treatment methods	Must be subjected to special treatment in compliance with official regulations. Refer to information in section 8 for exposure control.
14 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.

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15 SECTION 15: Regulatory information	
15.1. Safety, health and environmental regulations/legislation specific for the substance	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 substance.
16 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.