

FACTSHEET – NATURAL CBD PURE API

SWISS ORIGIN AND SWISS MADE

as of 01.09.2021



Product Description

- **Natural CBD Pure API** is a crystalline and pure cannabidiol (CBD) powder.
- **Natural CBD Pure API** is particularly suitable for extemporaneous formulations or for processes that require standardised products of consistent highest quality and properties.
- **Natural CBD Pure API** has a **purity of > 99.0% and contains no delta-9-tetrahydrocannabinol (Δ -9-THC)** and, therefore, has no psychotropic effect. Additionally, it is quantitatively tested for six known cannabinoid impurities.
- **Natural CBD Pure API** has a guaranteed content of > 98.0% CBD measured against certified reference standards.
- Each batch is tested for pesticides, aflatoxin and ochratoxin, as well as microbiological properties according to the current Ph. Eur. monograph.
- The powder is neutral in odour and taste.
- **Natural CBD Pure API** is not light-sensitive and can be processed under normal conditions at room temperature.
- **Natural CBD Pure API** is soluble at room temperature within a few minutes in:
 - all organic solvents
 - MCT oilSee solubility table on page 4.
- **Natural CBD Pure API** is free from:
 - Lactose
 - Gluten
 - Sugar
 - Artificial additives
 - Preservatives
- **Natural CBD Pure API** is obtained from hemp plants cultivated in Switzerland without pesticides and from natural plant extracts produced in Switzerland.

Company Portrait

LIPOMED AG is a private and internationally operating Swiss life science company with GMP/GDP and ISO 9001 certified pharmaceutical production facilities located near Basel and holds all necessary licenses for the production and distribution of medicinal products. It is dedicated to the research, development, manufacturing, and commercialisation of APIs and ethical pharmaceuticals with a particular focus on haematology, oncology, and other niche indications as well as customised contract manufacturing of special APIs.

Furthermore, LIPOMED is a worldwide leading manufacturer and supplier of analytical reference standards with ISO/IEC 17025 accreditation for testing and ISO 17034 accreditation for the production of reference material, issued by an independent American accreditation body.

The full traceability and quality of the plant materials and raw materials used is ensured by LIPOMED AG's close cooperation with two Swiss domiciled, established and recognised ISO 9001 certified Swiss companies specialised in the cultivation and extraction of cannabis including medicinal hemp, in particular: Marry Jane AG and Grünkraft AG.



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Quality Standard

- The pharmaceutical production of **Natural CBD Pure API** is carried out **in compliance with GMP standards according to ICH Q7**.
- **Natural CBD Pure API is analysed according to current DAC/NRF monograph (DAC C-052 Cannabidiol) and released according to current pharmaceutical standards** (see specifications on page 3).
- → **Natural CBD Pure API thus meets the API requirements for the production of CBD medicinal products in small quantities¹**.
- The analytical methods are **validated** for CBD and the results are **qualified against certified reference standards**.
- The manufacturing process of the starting material and the plant extract is carried out **in compliance with ISO 9001**.
- We offer full transparency on the origin of the hemp plant until the production of the **Natural CBD Pure API**.
- From the cultivation of the hemp plant to the processing and pharmaceutical production of the **Natural CBD Pure API**, we guarantee **“100% Swiss origin and Swiss made”**.

Manufacturing

- The pharmaceutical **production under GMP conditions** as well as the release according to DAC/NRF C-052 monograph of **Natural CBD Pure API** take place at LIPOMED AG in Switzerland.
- The manufacturing process has been validated, which guarantees the consistent quality of **Natural CBD Pure API**.
- The precursor stages of the pharmaceutical production of **Natural CBD Pure API** are carried out in an ISO 9001 controlled environment to guarantee quality and traceability at every stage, from cultivation to the finished substance.
- The plant extracts used to produce the **Natural CBD Pure API** originate from a certified Swiss hemp of the genetics **„Cannabis Sativa L. Fedora 17“** and are obtained through a gentle low-temperature extraction process.
- The hemp is grown in one of the most modern, largest and environmentally friendly facilities in Switzerland.
- No pesticides, herbicides or fungicides are used during the cultivation of the plants.

Intended Use

Who is **Natural CBD Pure API** suitable for?

- Pharmacies (extemporaneous preparation)
- Pharmaceutical industry
- Clinical research
- Veterinary industry
- Cosmetics industry
- Food industry
- Wholesale trading

in compliance with the relevant national legislation, such as Swiss legislation¹.

How can **Natural CBD Pure API** be used?

- As a raw material for extemporaneous preparations or house specialities in the pharmacy.
- As a component for ointments, creams, emulsions, etc.
- As a component for food supplements and nutritional products.

in compliance with the relevant national legislation, such as Swiss legislation¹.

¹ See Information sheet of Swissmedic „Products containing cannabidiol (CBD). Overview and implementation guide, 4th updated version, as of 21.04.2021“

SPECIFICATIONS OF NATURAL CBD PURE API

as of 01.09.2021

Product name:	Natural CBD Pure API	Molecular weight:	314.5 g/mol
Molecular formula:	$C_{21}H_{30}O_2$	Manufacturer:	LIPOMED AG
Remarks:	Powder, origin from plant product – 100% made in Switzerland	Retest Interval:	3 years
Art.-No.:	CBD-303	Storage condition:	room temperature

Specifications and analytical methods are based on DAC C-052

TEST	SPECIFICATION	METHOD
1. Appearance	White to off-white crystalline powder	Visual inspection
2. Identification	Identical to reference spectrum	IR-spectroscopy
3. Melting point	65 to 69 °C	Ph. Eur. 2.2.14
4. Optical rotation (ethanol)	-129.5 to -135.0	Ph. Eur. 2.2.7
5. Assay cannabidiol	98.0 to 102.0%	HPLC
6. Specified impurities:		HPLC
Δ 9-THC	≤ 0.10%	
Δ 8-THC	≤ 0.10%	
Cannabidiolic acid	≤ 0.10%	
Cannabinol	≤ 0.10%	
Cannabidivarin	≤ 0.5%	
Cannabidibutol	≤ 0.5%	
7. Single non-specified impurities	≤ 0.10%	HPLC
8. Total non-specified impurities	≤ 0.5%	HPLC
9. Total impurities	≤ 1.0%	HPLC
10. Sulphated ash	≤ 0.1%	Ph. Eur. 2.4.14
11. Water content	≤ 1.0%	Titration (Karl-Fischer)
12. Residual solvents:		Gas chromatography
Ethanol	≤ 5000 ppm	
Triethylamine	≤ 5000 ppm	
Heptane	≤ 5000 ppm	
13. Microbiological quality:		
TAMC	≤ 10 ³ CFU/g	Ph. Eur. 2.6.12
TYMC	≤ 10 ² CFU/g	Ph. Eur. 2.6.12
Specified microorganism		
E. Coli	Absent in 1 g	Ph. Eur. 2.6.13
14. Pesticides	Corresponds to Ph. Eur. 2.8.13	Ph. Eur. 2.8.13
15. Aflatoxin B ₁	≤ 2 µg/kg	Ph. Eur. 2.8.18
16. Ochratoxin A	≤ 80 µg/kg	Ph. Eur. 2.8.22

CHEMICAL DATA

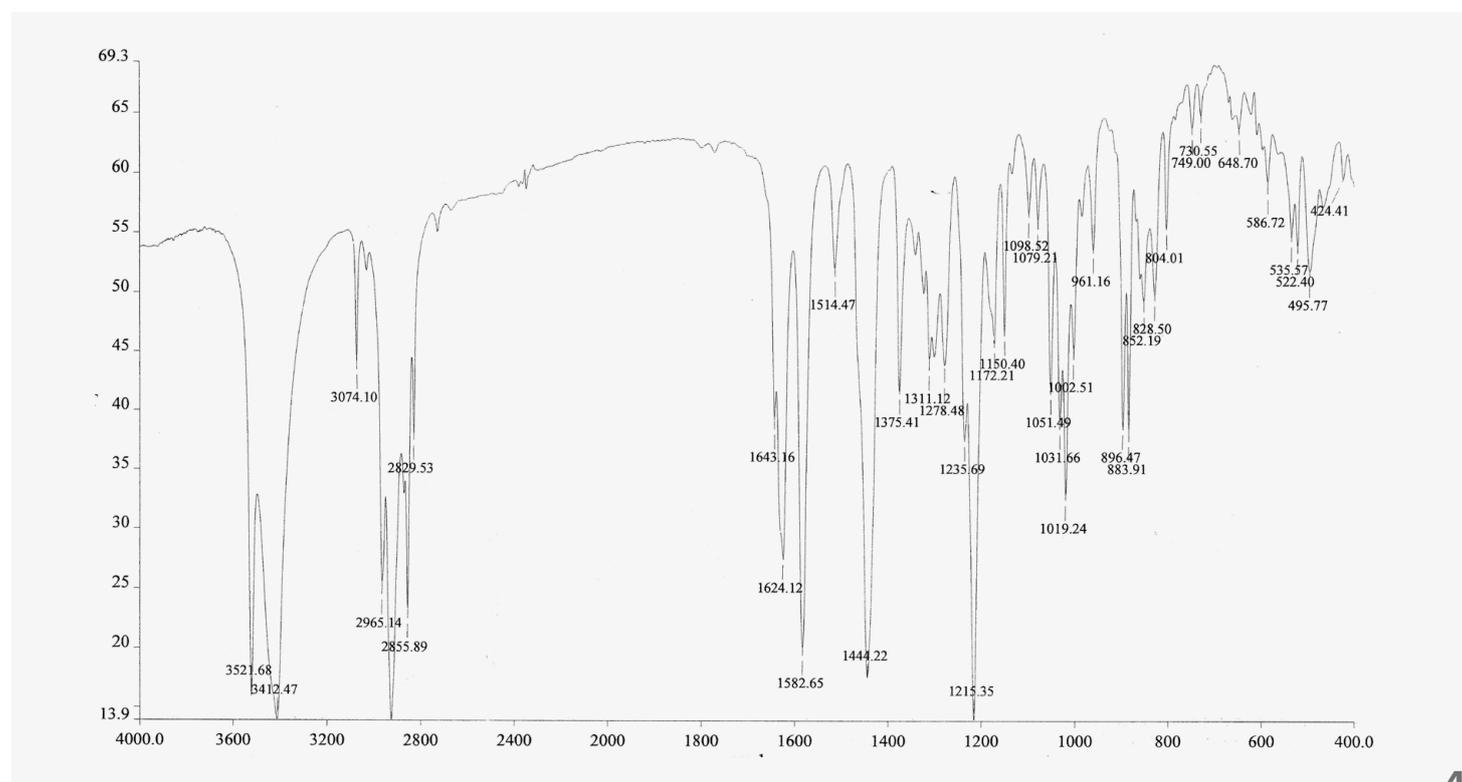
NATURAL CBD PURE API

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Solubility of Natural CBD Pure API at room temperature

Solvent	Solubility at room temperature mg/mL	Solvent	Solubility at room temperature mg/mL
Water	< 0.13	Chloroform	> 100
n-Decane	36.76	Dichloromethane	> 100
Isooctane	43.91	Acetonitrile	> 100
Heptane	64.6	Isopropyl acetate	> 100
IPA	> 100	Cyclohexane	> 100
1-Propanol	> 100	Methanol	> 100
Anisole	> 100	Ethanol	> 100
THF	> 100	p-Xylene	> 100
Toluene	> 100	1,4-Dioxane	> 100
Cumene	> 100	2-Butanone	> 100
Ethyl formate	> 100	MTBE	> 100
Diethyl ether	> 100	n-Hexane	> 100
1,2-Dimethoxyethane	> 100	NMPO	> 100
Acetone	> 100	Methylcyclohexane	> 100
Ethyl acetate	> 100	MeTHF	> 100
Isobutanol	> 100	MeTHF saturated with water	> 100

Example of an FTIR spectrum of Natural CBD Pure API

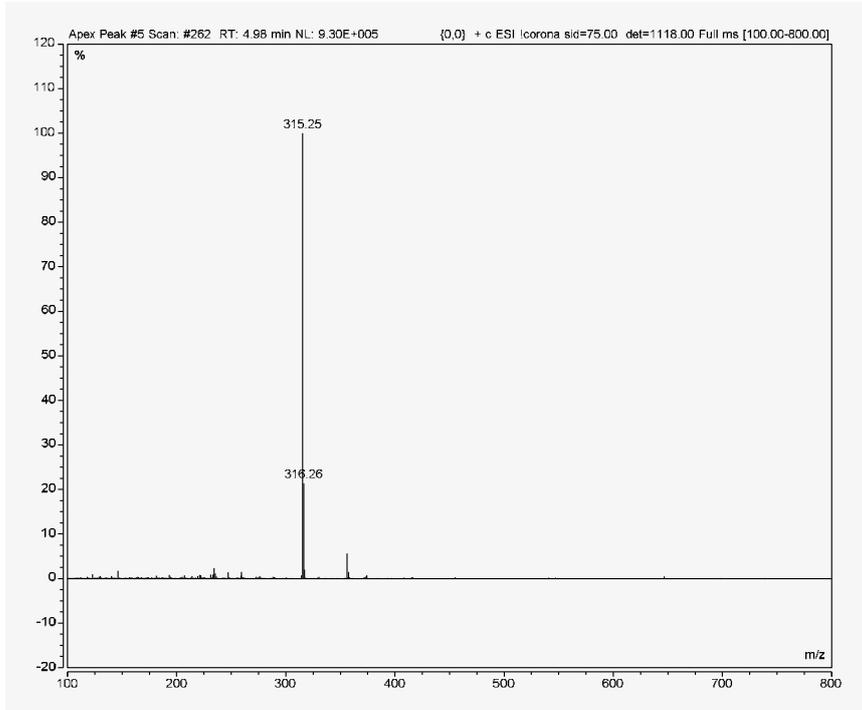


CHEMICAL DATA

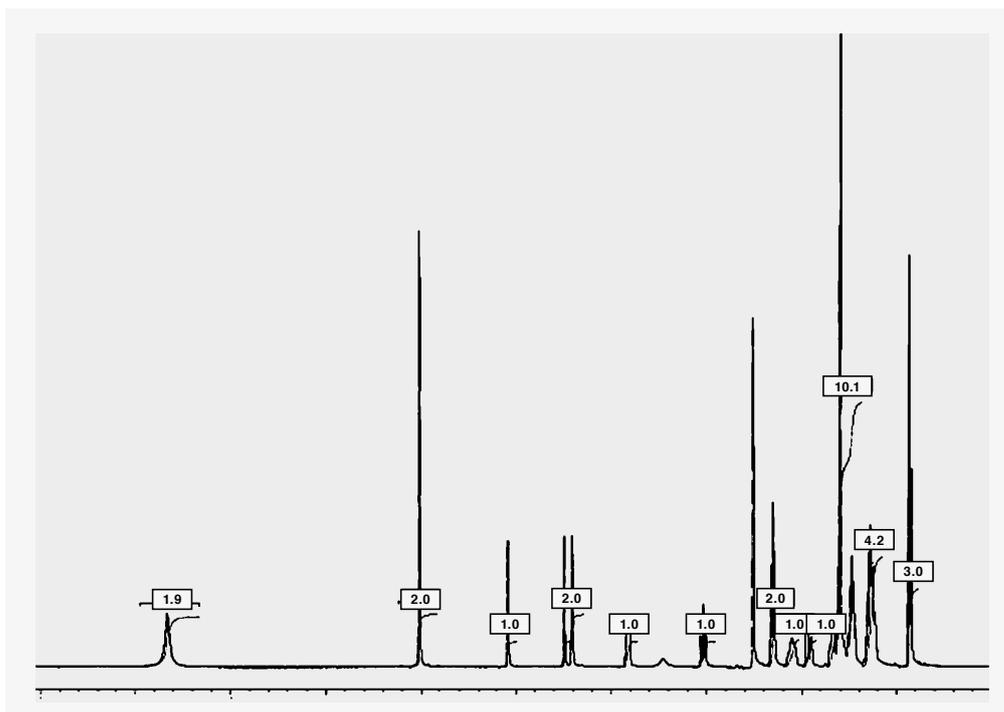
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Example of a mass spectrum of Natural CBD Pure API



Example of a NMR spectrum of Natural CBD Pure API

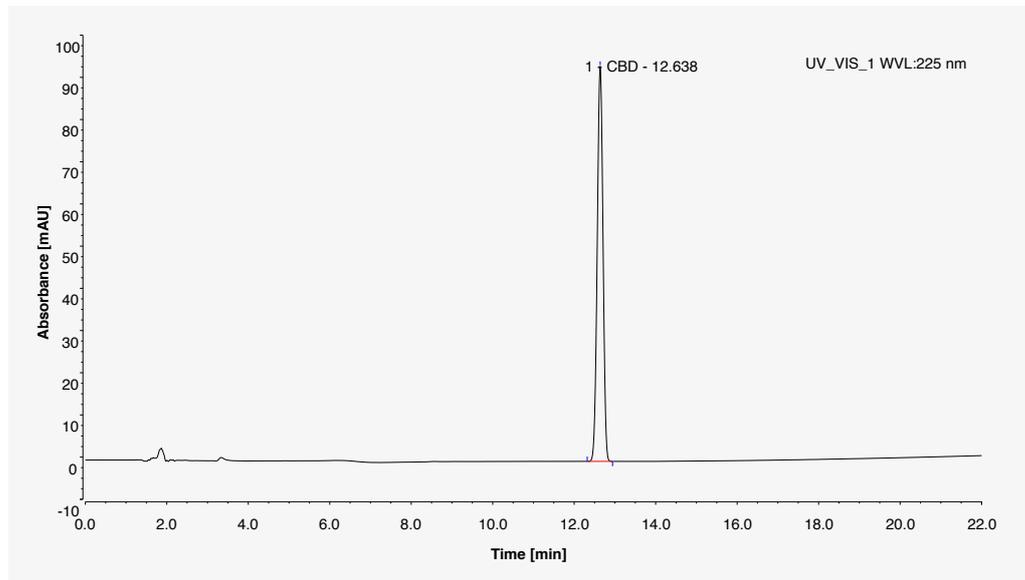


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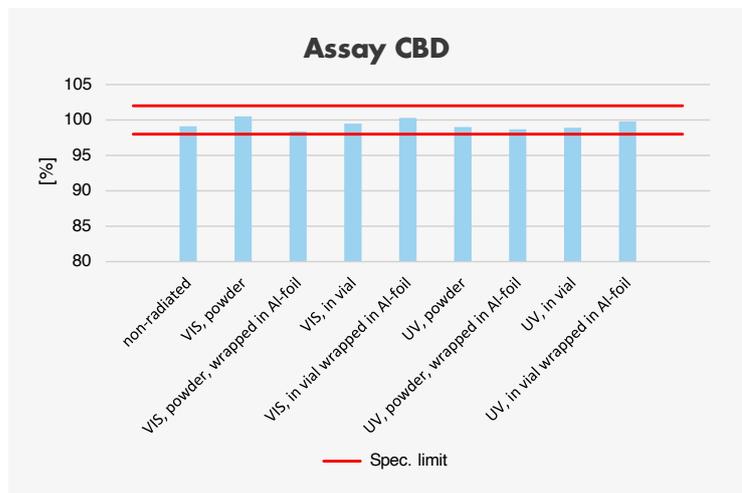
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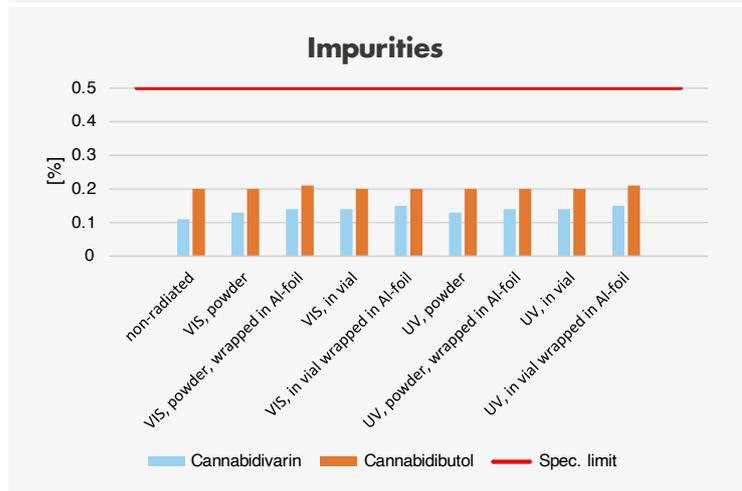
Example of a HPLC chromatogram of Natural CBD Pure API



Photostability of Natural CBD Pure API according to ICH Q1B



The CBD content lays within the specification limits of 98% to 102% for all irradiation variants (UV or VIS, powder or bottled, directly irradiated or packed in aluminium foil). No influence of light is noticeable.



The impurities remain unchanged and are independent of the irradiation variant.

The **Natural CBD Pure API** is therefore not light-sensitive.