



# CANNABIDIOL

API isolated from *Cannabis sativa* registered EU varieties



# 1.

## Cannabidiol: the background

Cannabidiol, more commonly known as CBD, is a **non-psychoactive** compound found in the cannabis plant.

**It is becoming increasingly popular due to its many potential therapeutic uses (e.g. epilepsy, pain and inflammation).**

**CBD was first isolated in 1940 by Dr. Roger Adams, an organic chemist at the University of Illinois. Since then, it has been studied extensively and its therapeutic uses have been clinically validated.**

CBD works by **interacting with the body's endocannabinoid system, which is responsible for regulating many of the body's functions, including mood, appetite, sleep, and more.**

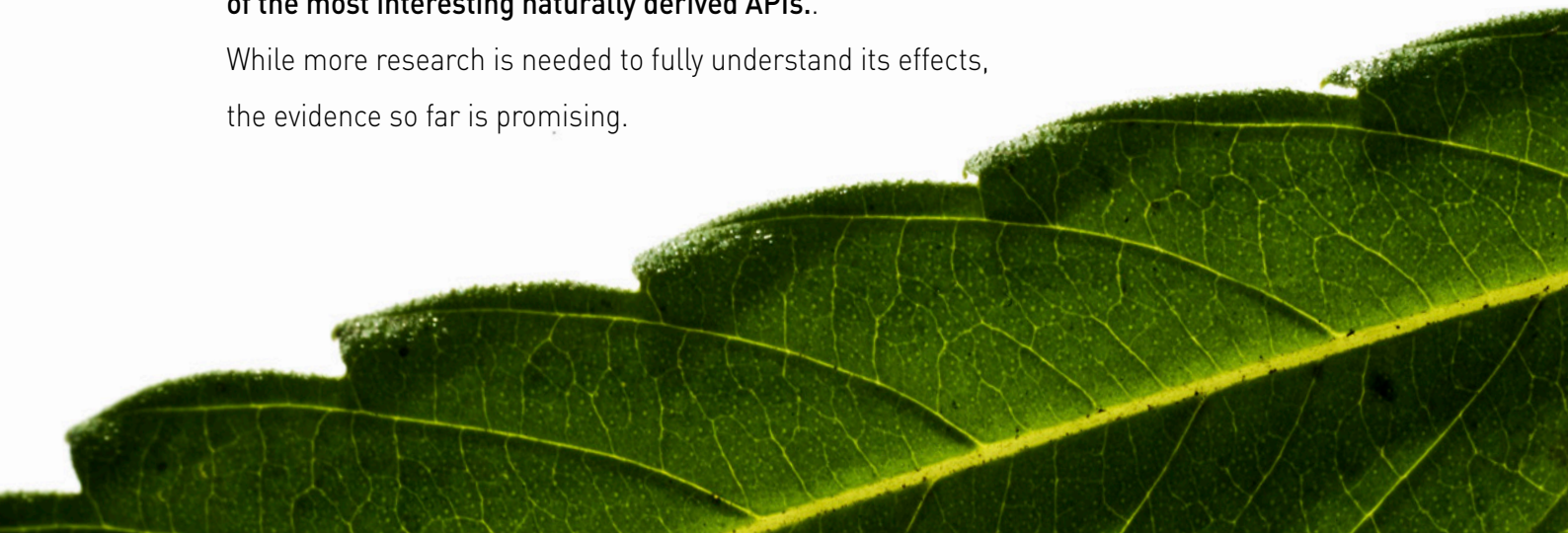
It is believed that CBD can help to balance the endocannabinoid system, which can lead to improved overall health.

**In recent years, CBD has been gaining more mainstream acceptance.** Naturally derived CBD is an API contained in several registered drug products, with the first example represented by Epidiolex®.

**CBD is being clinically studied in a wide range of conditions, including anxiety, depression, chronic pain, epilepsy and even certain types of cancer. It is also believed to have anti-inflammatory, antioxidant, and neuroprotective properties.**

With its many potential benefits, **CBD is quickly becoming one of the most interesting naturally derived APIs.**

While more research is needed to fully understand its effects, the evidence so far is promising.



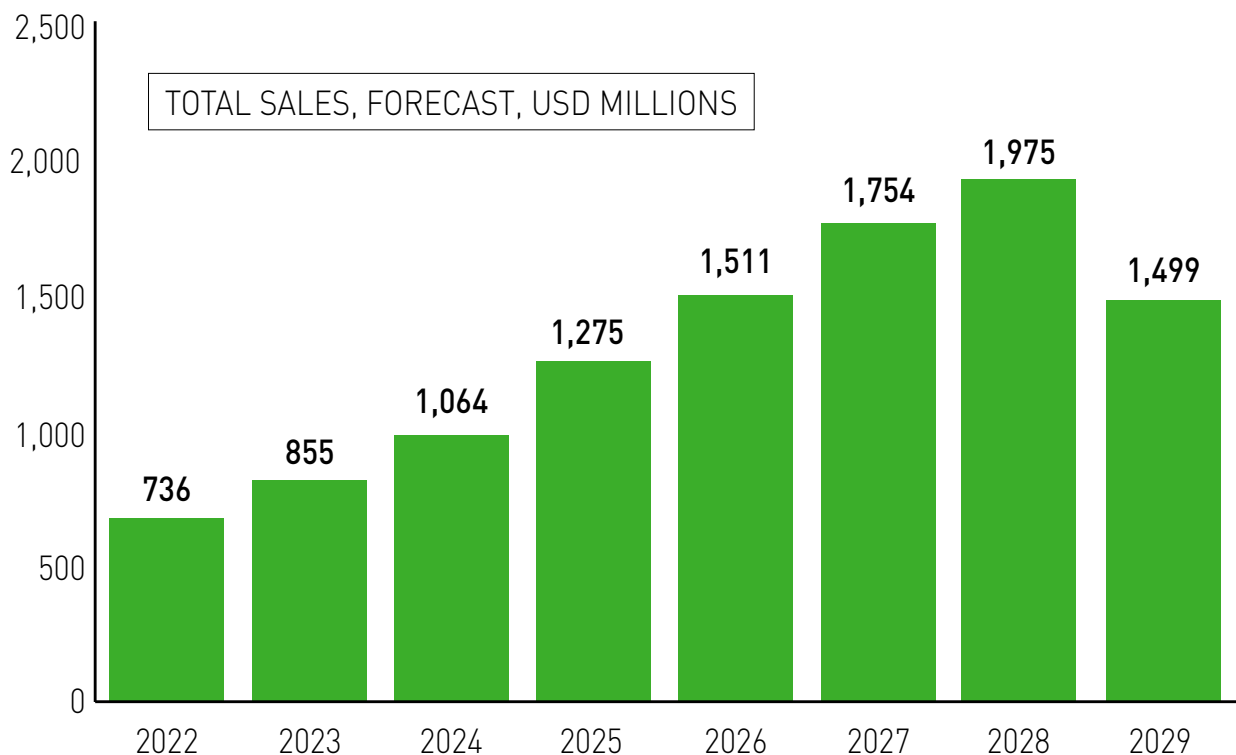
# 2.

## Cannabidiol: pharma market in EU

Currently CBD in EU is used either in registered pharmaceutical products or formulated by compounding pharmacies according to specialist prescriptions.

Source: Epidiolex/Sativex market share of originators

### Global sales of pharmaceutical products based on CBD API



Source: Globaldata

**This may represent an opportunity for companies to introduce innovative pharmaceutical products based on a high quality CBD API manufactured according to GMP with DMFs available for reference in main geographies.**

# 3.

## Indena's CBD: the origins

In 2021, Indena became the first company in Italy authorized by the Italian Ministry of Health to produce cannabinoid-based cannabis extracts.

The approval process continued, and Indena **also received GMP authorization from AIFA** (Italian pharmaceutical regulatory body), making it **one of the few companies in the world able to produce cannabidiol (CBD) for the pharmaceutical market.**

Building on this foundation, Indena reached **a second major milestone in 2024: becoming the first global API manufacturer to secure European CEP certification for its pharmaceutical-grade CBD extract.** This achievement further underscores our leadership and commitment to quality in the production of CBD for clinical and commercial use.

**The raw material is grown and processed in Italy, and the entire supply chain, which complies with the strict criteria set out in Italian regulations, is controlled, certified, and fully traced by the company.** Indena's traditional rigor in managing the production chain was a key factor in obtaining authorization.

**Indena uses registered varieties of *Cannabis sativa* with a THC level of less than 0.2% in accordance with European standards.** It also guarantees a residual **THC content of less than 0.02%, well below the limits defined by the FDA** (Food and Drug Administration) **and by DEA** (Drug Enforcement Administration). **This approach enabled Indena to promptly submit the DMF (Drug Master File) for this product to the FDA.**

**The biomass is processed at Indena's pharmaceutical plant,** regularly authorised by AIFA, inspected by the main international regulatory agencies (FDA, KFDA, PMDA and others) and ISO14001 Certified.

**All production is carried out in compliance with pharmaceutical GMP** (Good Manufacturing Practices), **in line with the highest quality standards that the company has always applied** which have been recognised by the international scientific community and consolidated over 100 years of business.



# 4.

## Indena's CBD: the specs

Indena's CBD is an API commercially available, obtained by extraction, isolation and purification from the plant\* and it appears as a crystalline white powder with the following standard specifications:

Crystalline white powder

HPLC CBD content: 98-102 %

Total impurities:  $\leq 0.80\%$

Impurities profile	Specifications
THC	$\leq 0,02\%$
Cannabidivarin	$\leq 0,15\%$
Butyl-CBD	$\leq 0,15\%$
CBD hydroxyquinone	$\leq 0,15\%$
Cannabinol	$\leq 0,15\%$
Others	$\leq 0,10\%$

\*EU accepted agricultural varieties with a THC level  $\leq 0.2\%$  w/w (non narcotic)





# 5.

## Cannabidiol: the italian regulatory framework

Even though *Cannabis sativa* is an agricultural commodity (European catalogue of accepted agricultural varieties) and CBD is a non-intoxicating cannabinoid, the handling of aerial parts for the extraction of derivatives meant for medical uses has to comply with controlled substances rules, in accordance, among others, with the UN Single Convention on Narcotic Drugs (1961).



THUS, WE ASSURE:

- + **Hemp growers are authorized by Ministry of Health**
- + **Full traceability from the plant to the final API is granted**
- + **Manufacturing site is authorized by AIFA and Ministry of Health**
- + **Export permit to ship the API abroad support every shipment**







# 6.

## Indena's CBD: the supply chain

In Indena's supply chain, **more traditional realities coexist with others with a strong innovative connotation**, expressed both at the cultivation level, through the use of advanced technology, and at the raw material manufacturing process level.



**The use of environmental sensors in the field, typical of precision agriculture, allows for more careful management of the cultivation: this way, in fact, human interventions on the crops are limited to actual needs and this translates into greater quality/healthiness of the product and in a lower impact on the environment.**

At the process level, technologically advanced solutions have been adopted which, alongside the more traditional ones, allow **greater efficiency in terms of saving resources and energy.**



