INDENA FIRST GLOBALLY TO SECURE EUROPEAN CEP FOR CBD

AFTER RECEIVING APPROVALS FROM THE ITALIAN MINISTRY OF HEALTH AND AIFA IN 2021, INDENA REACHES ANOTHER MAJOR MILESTONE FOR ITS PHARMACEUTICAL-GRADE CANNABIDIOL

Milan, 18th February 2025 - Indena achieves another milestone: it's the first global API manufacturer with European CEP certification for its CBD extract, which the company produces for clinical and commercial use.

The European Pharmacopoeia Certificate of Eligibility (CEP) is a document issued by the European Directorate for the Quality of Medicines (EDQM). It certifies the compliance of an active substance with the quality and safety specifications established by the European Pharmacopoeia.

This CEP certification underscores the high quality of Indena's CBD and the company's commitment to meeting the needs of customers worldwide seeking a quality- and safety- certified ingredient. Furthermore, Indena stands alone globally, as the only API manufacturer to have received this certification.

Indena previously received two key authorizations in 2021. The Italian Ministry of Health granted permission for the manufacture of cannabinoid-based cannabis extracts, while AIFA authorized the production of cannabidiol (CBD) for pharmaceutical use. Indena's CBD is derived from the flowers and aerial parts of *Cannabis sativa* L. through extraction and isolation. The raw material is grown and processed in Italy. The company controls, certifies, and fully traces the supply chain, ensuring compliance with stringent Italian regulations. Indena's rigorous management of the production chain was instrumental in securing authorizations from both Italian and European authorities.

Indena uses registered varieties of hemp 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.

Cecilia Nastro, Regulatory Affairs Department, says: *"This CEP certification represents a significant step forward for Indena. The extensive analytical work undertaken by our team, who meticulously examined our API and processes to meet the demanding standards of this European certification, demonstrates our commitment to delivering high-quality, reliable pharmaceutical ingredients. This achievement positions us well to meet the growing global demand for rigorously certified CBD products".*

Indena processes its hemp biomass in a pharmaceutical-grade facility authorized by AIFA and inspected by leading international regulatory agencies, including the FDA, KFDA, and PMDA. All production adheres to pharmaceutical Good Manufacturing Practices (GMP), reflecting Indena's longstanding commitment to the highest quality standards, recognized by the international scientific community.

Cannabidiol (CBD) is an active pharmaceutical ingredient used in products approved for treating seizures associated with rare childhood epilepsy syndromes, including Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex. CBD is also undergoing clinical development for other forms of epilepsy and is being studied for its therapeutic potential in schizophrenia, other psychiatric disorders, neurological diseases, and autoimmune/inflammatory conditions[1].

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1. C. Michael White, PharmD, A Review of Human Studies Assessing Cannabidiol's (CBD) Therapeutic Actions and Potential, J Clin Pharmacol 2019, 59(7), 923-934.

offer different capacities for products at the highest containment level (OEL 1ng/m3 or OEB5); two spray dryers, large and a mid-size, working with organic solvents; a 20-lt hydrogenator and a 250-liter hydrogenator to satisfy a wider demand for this kind of chemistry. Find more on indena.com

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