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Leiutis Pharma announces CDSCO approval for global-first synthetic CBD therapy to cure mild to moderate anxiety disorders

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First globally approved synthetic cannabidiol oral solution 150mg/ml prescription by psychiatrists only

Hyderabad-based Leiutis Pharmaceuticals LLP, a speciality therapeutics company, has announced that the Central Drugs Standard Control Organisation (CDSCO) has granted regulatory approval to collaboration partner Zenara Pharma to manufacture its proprietary Synthetic Cannabidiol Oral Solution 150 mg/mL for the management of mild to moderate anxiety disorders when used in conjunction with cognitive behavioural therapy (CBT).

The product is to be prescribed only by psychiatrists. The approval is based on a successful Phase III clinical trial conducted in India in accordance with CDSCO requirements and will be followed by a Phase IV study.

Leiutis said it marks the world's first regulatory approval of a fully synthetic cannabidiol oral solution for the management of mild to moderate anxiety disorders. The product was researched, developed, patented and clinically validated entirely in India.

The product combines a synthetic cannabidiol active pharmaceutical ingredient (API), developed by Biophore India Pharmaceuticals, with Leiutis' proprietary nanodispersible drug delivery platform, manufactured at Zenara's CDSCO-, FDA-, and EU-compliant facilities.

The company said the product represents end-to-end pharmaceutical innovation achieved in India, spanning API development, drug delivery, clinical development, and regulatory approval.

The approval comes at a time when anxiety disorders remain a significant public-health challenge in India.