Indoco Remedies' Lacosamide Oral Solution, 10 mg/mL, Gets FDA Green Light

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Indoco Remedies Ltd. has received final approval from the US Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Lacosamide Oral Solution USP, 10 mg/mL.

The approval allows the company to market a generic version of Vimpat Oral Solution, 10 mg/mL, the reference listed drug of UCB, Inc., in the United States.

Lacosamide Oral Solution USP, 10 mg/mL, has been found to be bioequivalent and therapeutically equivalent to the reference product. The drug will be manufactured at Indoco Remedies' facility located in the Verna Industrial Area, Goa, India.

The product is indicated for the treatment of partial-onset seizures and primary generalised tonic-clonic seizures in adults and children aged four years and above with epilepsy.

The company reported a turnover of approximately $180 million and employs over 6,000 people worldwide, including more than 400 scientists and field professionals supporting its research, development, and commercial operations.

With this approval, Indoco Remedies further strengthens its U.S. generics portfolio, reinforcing its position in regulated markets while expanding access to affordable epilepsy treatments for patients.