

Indoco Remedies receives US FDA final approval for its ANDA for lacosamide oral solution USP, 10 mg/mL

Our Bureau, Mumbai

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Indoco Remedies Ltd., a fully integrated, research-oriented pharmaceutical company, announced final approval from US FDA for company's Abbreviated New Drug Application (ANDA) for lacosamide oral solution USP, 10 mg/mL, to market, a generic equivalent to the reference listed drug (RLD), Vimpat oral solution, 10 mg/mL, of UCB, Inc. (UCB).

Lacosamide oral solution USP, 10 mg/mL, is bioequivalent and therapeutically equivalent to the reference listed drug, Vimpat oral solution, 10 mg/mL, of UCB, Inc. (UCB).

Lacosamide oral solution USP, will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India.

Lacosamide oral solution is used to treat partial onset seizures and primary generalized tonic-clonic seizures in adults and children with epilepsy who are at least 4 years old.

Commenting on the achievement, Aditi Panandikar, managing director said, "We are excited about the ANDA approval for lacosamide oral solution USP, 10 mg/ml. This approval further reinforces our commitment to delivering high-quality healthcare to patients worldwide."

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The company's turnover is US\$ 180 million with a human capital of over 6,000 employees, including over 400 skilled scientists and field staff who are the strength of the organization.