



Indoco Remedies Receives USFDA Final ANDA Approval for Lacosamide Oral Solution USP

Indoco Remedies Limited ₹ 217.15 | +1.99%

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Indoco Remedies received final USFDA approval for its Abbreviated New Drug Application (ANDA) for Lacosamide Oral Solution USP, 10 mg/mL. This generic product is equivalent to UCB, Inc.'s Vimpat Oral Solution. The drug will be manufactured in India. Managing Director Aditi Panandikar highlighted the approval reinforces the company's commitment to global healthcare.

What this means for investors?

Sentiment Analysis:

The USFDA final ANDA approval for a generic drug is a positive development for the company, indicating successful product development and regulatory compliance, which is expected to boost its market presence.

Impact Assessment:

The approval of a generic drug is a significant step for Indoco Remedies, potentially increasing its revenue and market share in the epilepsy treatment segment. However, the exact financial impact will depend on market adoption and competition.

More Details on This News

Indoco Remedies Limited has received final approval from the USFDA for its Abbreviated New Drug Application (ANDA) for Lacosamide Oral Solution USP, 10 mg/mL. This generic equivalent to UCB, Inc.'s Vimpat Oral Solution, 10 mg/mL, is used for treating partial onset seizures and primary generalized tonic-clonic seizures in adults and children with epilepsy aged 4 years and older.

The Lacosamide Oral Solution USP will be manufactured at Indoco Remedies' facility in Verna, Goa, India. Ms. Aditi Panandikar, Managing Director, expressed excitement about the approval, stating it reinforces the company's commitment to delivering high-quality healthcare globally.

Indoco Remedies is an integrated, research-oriented pharmaceutical company with a global presence, reporting a turnover of US\$ 180 million and employing over 6000 individuals. The company operates 11 manufacturing facilities, including 7 for finished dosage forms (FDFs) and 4 for active pharmaceutical ingredients (APIs), supported by a state-of-the-art R&D Centre and a CRO facility. Its facilities are approved by major regulatory authorities, including the USFDA and UK-MHRA. Indoco serves both Indian and international markets, generating over 106 million prescriptions annually from healthcare professionals across various specialties. The company has 10 domestic marketing divisions and a strong brand portfolio across multiple therapeutic segments. On the international front, Indoco collaborates with major generic companies worldwide.

Historical Stock Returns for Indoco Remedies Limited

1 Day	5 Days	1 Month	6 Months	1 Year
+2.16%	+3.40%	-5.68%	-32.97%	-11.27%