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Indoco Remedies Shares Soar 7% on Securing USFDA Final Approval

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Shares of Indoco Remedies Limited soared 7% on 30 January after the company announced securing final approval from the USFDA.

In its regulatory filing, the company said that it 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, adding to its US generics portfolio.

According to an exchange filing, the approval permits Indoco to market a generic counterpart of Vimpat Oral Solution, 10 mg/mL, UCB, Inc.'s reference-listed medication, in the United States market. The product was shown to be bioequivalent and therapeutically equivalent to the branded formulation.

Lacosamide Oral Solution is used to treat partial-onset seizures and primary generalised tonic-clonic seizures in adults and children with epilepsy aged four years and older. According to Indoco, the authorised product would be manufactured in the company's Goa site in Verna.

Aditi Panandikar, managing director of Indoco Remedies, commented on the development, saying that the clearance confirms the company's commitment to supplying high-quality healthcare products globally while also strengthening its regulated markets business.

In Q2FY26, the company's net loss was reduced to Rs 8 crore from Rs 9.6 crore the previous year. In the September quarter, revenue climbed by 12% to Rs 485 crore from Rs 433 crore in the second quarter of the last fiscal year. EBITDA also improved by 6.6% to Rs 43.4 crore from Rs 41 crore the previous year. Its margins fell slightly to 9% from 9.4% in Q2 Fy25.

At 3:30 pm, the shares of Indoco Remedies closed 1.99% higher at Rs 217.15 on NSE.

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