Indoco Remedies shares gain over 8.5% post USFDA approval for Lacosamide oral solution

Indoco Remedies gained over 8.5% after USFDA approved its Lacosamide Oral Solution, a generic of Vimpat, boosting its US portfolio and reinforcing global healthcare commitment.

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Shares of Indoco Remedies Limited gained more than 8.5% on Friday, January 30, after it said it has secured the 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, marking another addition to its US generics portfolio.

In an exchange filing, the company said the approval allows Indoco to market a generic equivalent of Vimpat Oral Solution, 10 mg/mL, the reference listed drug of UCB, Inc., in the US market. The product has been found to be bioequivalent and therapeutically equivalent to the branded formulation.

Lacosamide Oral Solution is used in the treatment of partial onset seizures and primary generalised tonic-clonic seizures in adults and children aged four years and above with epilepsy. The approved product will be manufactured at Indoco's Goa facility in Verna, the company said.

Commenting on the development, Aditi Panandikar, managing director of Indoco Remedies, said the approval reinforces the company's commitment to delivering high-quality healthcare products globally and strengthens its regulated markets business.

The company's net loss for Q2FY26 improved to ₹8 crore from ₹9.6 crore in the year ago period. Revenue increased 12% to ₹485 crore from ₹433 crore in the second quarter last fiscal and EBITDA increased 6.6% in the September quarter to ₹43.4 crore from ₹41 crore last year. Its margins contracted marginally to 9% from 9.4% in Q2FY25.

Following the announcement, shares of the pharma company surged to reach intraday highs of ₹229.64, the stock has however pared its gains since then and is trading at ₹217.47 as of 1.43 pm, still 2.14% above its opening price.