

Indoco Remedies gains on receiving USFDA nod for Rivaroxaban tablets

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Indoco Remedies rose 1.56% to Rs 296.15 after the company announced it had received final approval from the USFDA for its ANDA for Rivaroxaban tablets USP.

The approval covers strengths of 2.5 mg, 10 mg, 15 mg, and 20 mg. The approved tablets are bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Xarelto Tablets, manufactured by Janssen Pharmaceuticals, Inc.

The product will be manufactured at Indocos facility in Verna Industrial Area, Goa (L-14, Verna, Goa 403722).

Rivaroxaban is an oral anticoagulant used for the treatment and prevention of venous thromboembolism (VTE) a serious condition involving blood clots in the veins, which can lead to complications such as pulmonary embolism.

Commenting on the development, Aditi Panandikar, managing director of Indoco Remedies, said, Besides reflecting the capability of Indoco Remedies to deliver products of high-quality standards, this development also provides impetus to our growth aspirations in an important market such as the US.

Indoco Remedies is engaged in the manufacturing and marketing of formulations (finished dosage forms) and active pharmaceutical ingredients (APIs).

The company had reported a consolidated net loss of Rs 40.39 crore in the quarter ended March 2025 as against net profit of Rs 22.70 crore during the previous quarter ended March 2024. Sales declined by 12.57% to Rs 383.89 crore in Q4 FY25 over Q4 FY24.

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