

Indoco Remedies gets USFDA nod for generic Rivaroxaban tablets; eyes growth in US Market

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Mumbai-based Indoco Remedies Ltd. has secured final approval from the US Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) to market Rivaroxaban Tablets USP in strengths of 2.5 mg, 10 mg, 15 mg, and 20 mg. The product is the generic equivalent of Janssen Pharmaceuticals' blockbuster

anticoagulant, Xarelto, and will be manufactured at Indoco's Verna, Goa facility.

The approved Rivaroxaban tablets are bioequivalent and therapeutically equivalent to Xarelto and are indicated for the treatment of venous thromboembolism (VTE). This approval marks another milestone in Indoco's push into the US generics market, one of the most lucrative pharmaceutical markets globally.

Commenting on the development, Indoco Remedies' Managing Director Aditi Panandikar 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 a fully integrated, research-driven pharmaceutical company with a global footprint, generating over 106 million prescriptions annually in India alone. The company operates 11 manufacturing facilities — seven for finished dosage forms (FDFs) and four for active pharmaceutical ingredients (APIs) — all of which are approved by top global regulatory agencies including the USFDA and UK-MHRA.

With a turnover of \$180 million and a workforce of more than 6,000 employees, Indoco is known for popular domestic brands such as Cyclopam, Febrex Plus, Sensodent-K, Karvol Plus, ATM, Oxipod, and Cital. Internationally, the company partners with large generics players to expand its market reach across multiple geographies.

The latest USFDA approval strengthens Indoco's product portfolio in the regulated market and could open up significant revenue opportunities as Rivaroxaban continues to be a widely prescribed oral anticoagulant in the US.