Indoco Remedies receives final ANDA approval from USFDA for Rivaroxaban Tablets

13 August 2025

Indoco Remedies Ltd. announced final approval of the Company's Abbreviated New Drug Application (ANDA) for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg, to market a generic equivalent to the reference listed drug (RLD), Xarelto Tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen), from USFDA.

Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg are bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xarelto Tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen).

Rivaroxaban Tablets USP, will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India. Rivaroxaban is used for the treatment of venous thromboembolism (VTE).

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

Commenting on the achievement, Ms. Aditi Panandikar, Managing Director 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."