Indian Pharma Post

Indoco Remedies receives final USFDA approval for rivaroxaban tablets

Rivaroxaban is used to treat venous thromboembolism

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Indoco Remedies Ltd. has received final approval from the USFDA for its 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, 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 and will be manufactured at Indoco's facility in Verna, Goa, India.

Rivaroxaban is used to treat venous thromboembolism (VTE).

Commenting on the achievement, 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."