Business Standard

Indoco Remedies receives USFDA approval for Rivaroxaban Tablets

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Indoco Remedies 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).

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