



PRESS RELEASE

Indoco Remedies receives final ANDA approval from USFDA for Varenicline Tablets, 0.5 mg and 1 mg

Mumbai, Oct' 30, 2024: Indoco Remedies Ltd. announced the final approval of the Company's Abbreviated New Drug Application (ANDA) for Varenicline Tablets, 0.5 mg and 1 mg, to market a generic equivalent to the reference listed drug (RLD), Chantix Tablets, 0.5 mg and 1 mg, of PF Prism C.V. (PF) from USFDA.

Varenicline Tablets, 0.5 mg and 1 mg bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Chantix Tablets, 0.5 mg and 1 mg, of PF Prism C.V. (PF).

This product, Varenicline Tablets, 0.5 mg and 1 mg will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India. Varenicline is used to aid smoking cessation treatment.

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."

About Indoco Remedies Limited:

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The Company's turnover is US\$ 212 million with a human capital of over 6000 employees, including over 400 skilled scientists and field staff who are the strength of the organization.

The Company has 11 manufacturing facilities, 7 for FDFs and 4 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by most of the Regulatory Authorities including USFDA and UK-MHRA. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 106 million prescriptions annually from over 2,35,000 doctors belonging to various specialties. Indoco has 8 domestic marketing divisions a strong brand portfolio in various therapeutic segments including Gastro-intestinal, Respiratory, Anti-Infective, Stomatologicals, Ophthalmic, Nutritionals, Cardiovascular, Anti-Diabetics, Pain Management, Gynaecology etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Karvol Plus, ATM, Oxipod, Cital, Sensiform, Sensodent-KF, Aloja, Glychek, Kidodent, Subitral, Rexidin, MCBM 69, Methycal, Dropizine, Noxa, Homide, Cal-Aid, etc. On the international front, Indoco has tie-ups with large generic companies across the globe.

For more details on Indoco, you may visit www.indoco.com

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