



PRESS RELEASE

Indoco Remedies receives final ANDA approval from USFDA for Pregabalin capsules

Mumbai, May 21, 2024: Indoco Remedies Ltd. announced the receipt of final approval from the USFDA for Abbreviated New Drug Application (ANDA) for Pregabalin capsules 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300mg. This is a generic equivalent of the Reference Listed Drug, Lyrica® Capsules 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300 mg, of Upjohn US 2 LLC.

This product, Pregabalin capsules will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India. Pregabalin is used for Neuropathic pain associated with diabetic peripheral neuropathy and spinal cord injury, Postherpetic neuralgia and Fibromyalgia.

Commenting on the achievement, **Ms. Aditi Panandikar, Managing Director** said, “This development marks a significant milestone for us and is a testament to our commitment to quality and regulatory compliance. We remain focused on quality, excellence and delivering value to our stakeholders.”

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, Sensoform, 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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