



PRESS RELEASE

Indoco Remedies receives tentative ANDA approval from USFDA for Canagliflozin and Metformin Hydrochloride Tablets

Mumbai, June 06, 2024: Indoco Remedies Ltd. announced the receipt of tentative approval from the USFDA for Abbreviated New Drug Application (ANDA) for Canagliflozin and Metformin Hydrochloride Tablets, 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, and 150 mg/1000 mg, a generic equivalent of Invokamet® Tablets, 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg and 150 mg/1000 mg.

This product, Canagliflozin and Metformin Hydrochloride Tablets, will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India. Canagliflozin and Metformin Hydrochloride Tablets are used to treat type 2 diabetes mellitus.

Commenting on the achievement, **Ms. Aditi Panandikar, Managing Director** said, “We are excited to receive tentative approval from the USFDA for our Canagliflozin and Metformin Hydrochloride Tablets. This milestone underscores our commitment to bringing affordable and effective treatment options to patients managing type 2 diabetes.”

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, Subital, 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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