



PRESS RELEASE

Indoco Remedies receives final ANDA approval from the USFDA for Cetirizine Hydrochloride Tablets USP, 10 mg (OTC)

Mumbai, October 4, 2024: Indoco Remedies Limited announced the receipt of final approval from the USFDA for Abbreviated New Drug Application (ANDA) for Cetirizine Hydrochloride Tablets USP, 10 mg (OTC), a generic equivalent of the Reference Listed Drug, Zyrtec Allergy Tablets, 10 mg of Johnson & Johnson Consumer Inc.

Cetirizine Hydrochloride Tablets USP, 10 mg will be manufactured by Indoco, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India. Cetirizine is used for relief of symptoms of hay fever and other allergic conditions.

Commenting on the achievement, **Ms. Aditi Panandikar, Managing Director** said, **“This approval is a testament to Indoco’s commitment to delivering high-quality and affordable healthcare solutions to global markets. We are proud to contribute to providing effective allergy relief medicines and remain focused in expanding our portfolio in the OTC space.”**

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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