



PRESS RELEASE

USFDA successfully completes inspection at Indoco's API manufacturing facility at Patalganga with zero observations

September 19, 2025, Mumbai: Indoco Remedies Limited announced today that the United States Food and Drug Administration (USFDA) successfully completed inspection of its Active Pharmaceutical Ingredients (API) manufacturing facility at Patalganga, Navi Mumbai. The inspection concluded with zero form 483 observations, reflecting the company's commitment to the highest standards of quality, regulatory compliance and operational excellence.

“This successful USFDA inspection is a testament to the strong quality culture and compliance in every process and every product. We remain committed to strengthening our systems to deliver safe and efficacious medicines across the globe,” **said Ms. Aditi Panandikar, Managing Director, Indoco Remedies Limited.**

About Indoco Remedies Limited:

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The Company's turnover is US\$ 180 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 2,40,000 doctors belonging to various specialties. Indoco has 10 domestic marketing divisions, a strong brand portfolio in various therapeutic segments including Gastro-intestinal, Respiratory, Anti-Infectives, 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, Dropizin, Noxa, Homide, Cal-Aid, Ninaf, Cital-Ui, Otorex, 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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