



PRESS RELEASE

Approval of Glycopyrrolate ANDA filed from Indoco's Goa Plant II

November 1, 2019, Mumbai: Abbreviated New Drug Application (ANDA) for Glycopyrrolate Injection 0.2 mg/ml filed from Indoco's Goa Plant II on behalf of its partner in the US, has been approved by the United States Food & Drug Administration (USFDA). Glycopyrrolate is indicated for use as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions. The market size of this product in the US is US\$ 120 million.

Commenting on this encouraging development, **Ms. Aditi Kare Panandikar, Managing Director – Indoco Remedies Ltd.**, said, "This is the first injectable ANDA approval from our sterile facility (Goa II) after resolution of the Warning Letter. This ANDA has been filed through our partner in US and the product is slated for launch in the last quarter of the current financial year."

About Indoco Remedies Limited:

Indoco Remedies Ltd., headquartered in Mumbai, is a fully integrated, research-oriented pharma Company with presence in 55 countries. Indoco, a USD 140 million Company, employs over 6000 people including more than 300 skilled scientists.

The Company has 9 manufacturing facilities, 6 of which are for FDFs and 3 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by USFDA, UK-MHRA, TGA-Australia, Cofepris – Mexico, etc. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 70 million prescriptions annually from around 3,10,000 doctors belonging to various specialties. Indoco has 9 domestic marketing divisions with a strong brand portfolio in various therapeutic segments including Respiratory, Anti-Infective, Dental Care, Pain Management, Gastro-intestinal, Ophthalmic, Cardiovascular, Anti-Diabetics, Anti-Obesity, etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Oxipod, Cital, ATM, Cloben-G, Sensoform, Sensodent-KF, Karvol Plus, Glychek, Kidodent, Carmicide, Bactogard, etc. On the international front, Indoco has tie-ups with large generic companies like Watson (Actavis) – USA and ASPEN-South Africa.

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

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