



PRESS RELEASE

USFDA clears Indoco's Goa Plant II & III

July 26, 2019, Mumbai: Indoco Remedies announced today that it has received the Establishment Inspection Report (EIR) from the US Food and Drug Administration (USFDA) for their sterile facility (Plant II) and solid dosages facility (Plant III) at Verna, Goa. The inspection was held from 27th May, 2019 to 4th June, 2019, where the Company had received 4 observations (483s).

Commenting on this positive development, **Ms. Aditi Kare Panandikar, Managing Director – Indoco Remedies Ltd.** said, “We are happy to receive the EIR in less than two months from the date of inspection. This is encouraging, as the site has been endorsed with the VAI status twice this year, by the US Regulators. The recent inspection was a Pre-Approval Inspection for 3 ANDAs of injectable products filed through our partners.”

The Company has 33 ANDAs pending for approval, out of which, 17 are for ophthalmics, 5 are for injectables and 11 are for solid dosages from the site.

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 5500 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, MCC-South Africa, 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

For Media Inquiries Please Contact:

Vilas V. Nagare

Mobile: 9820215745

E-mail: vilasn@indoco.com / corpcom@indoco.com