



# PRESS RELEASE

## **Indoco's API mfg. facilities successfully clear USFDA inspection**

**18 May, 2018, Mumbai:** Indoco Remedies Limited announced today, the successful completion of USFDA inspection at its API manufacturing facilities at Patalganga and Rabale, Navi Mumbai. The routine FDA inspection was conducted at Patalganga facility from 7<sup>th</sup> to 11<sup>th</sup> May, 2018 and Kilo Lab facility at Rabale from 14<sup>th</sup> to 17<sup>th</sup> May, 2018.

During the audit, the FDA thoroughly inspected Indoco's entire quality management systems to ensure compliance with federal regulations. The inspection included a review of production facility, processes and procedures, training records, quality systems and control procedures.

The Kilo Lab facility received zero 483s from the agency, while its API plant at Patalganga cleared the inspection with 3 observations; none of them are critical or pertain to data integrity.

### **About Indoco Remedies Limited:**

Indoco Remedies Ltd., headquartered in Mumbai, is a fully integrated, research-oriented Indian Pharma Company with presence in 55 countries. Indoco, a USD 165 million company, employs over 5000 people including over 300 skilled scientists.

The company has 9 manufacturing facilities, out of which 6 are for finished dosages and 3 for APIs, supported by a state-of-the-art R&D centre at Rabale, Navi Mumbai. The facilities have been approved by various regulatory authorities such as, USFDA, UK-MHRA, SUKL-Czech Republic, Cofepris – Mexico, TGA-Australia, JAZMP- Slovenia, MCC-South Africa, NDA-Uganda, TFDA-Tanzania, SBD-Yemen, MOH-Ukraine, PPB-Kenya and FDA-Ghana.

For more details on Indoco, you may visit [www.indoco.com](http://www.indoco.com).

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