



# PRESS RELEASE

## **Indoco Remedies receives final ANDA approval from the USFDA for Lofexidine Tablets 0.18 mg with Competitive Generic Therapy designation**

**Mumbai, August 21, 2024:** Indoco Remedies Limited (“Indoco”) announced the receipt of final approval from the USFDA for Abbreviated New Drug Application (ANDA) for Lofexidine Tablets 0.18 mg to market a generic equivalent of Lucemyra Tablets, 0.18 mg of USWM, LLC.

Indoco has been granted a Competitive Generic Therapy (CGT) designation by the USFDA and being the first approved generic, is eligible for 180 days of CGT exclusivity for Lofexidine Tablets, 0.18 mg (“Product”) in the USA. This exclusivity will begin to run from the date of the first commercial marketing of the product. Indoco intends to launch the product immediately in the USA.

This product will be manufactured by Indoco at its manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India.

This product is indicated for mitigation of symptoms associated with acute withdrawal from opioids and for facilitation of the completion of opioid discontinuation treatment.

As per IQVIA Health data, the sales of the product are around USD 15.59 million with an expected growth of 38%.

Commenting on the achievement, **Ms. Aditi Panandikar, Managing Director** said, “We are extremely pleased with this development as this strengthens our position in the US market, driving us closer to expanding our reach in the US.”

### **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, Sensiform, 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](http://www.indoco.com)

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