



October 30, 2024

To The Manager Listing Department <b>National Stock Exchange of India Limited</b> 'Exchange Plaza', C - 1, Block G, Bandra-Kurla Complex, <u>Bandra (E), Mumbai 400051.</u> Scrip Code: INDOCO	To <b>BSE Limited</b> Corporate Relationship Department 1 <sup>st</sup> Floor, New Trading Ring, Phiroze Jeejeebhoy Towers Dalal Street <u>Mumbai 400001</u> Scrip Code : 532612
---	---

Dear Sir/Madam,

**Sub: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements), Regulations 2015 ('Listing Regulations').**

We are pleased to announce the final approval of the Company's Abbreviated New Drug Application (ANDA) for Varenicline Tablets, 0.5 mg and 1 mg, to market a generic equivalent to the reference listed drug (RLD), Chantix Tablets, 0.5 mg and 1 mg, of PF Prism C.V. (PF) from USFDA.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the Listing Regulations.

The above is for your information and dissemination.

Thanking you,  
Yours faithfully,  
For Indoco Remedies Limited

Ramanathan Hariharan  
Company Secretary & Head Legal





## PRESS RELEASE

### Indoco Remedies receives final ANDA approval from USFDA for

#### Varenicline Tablets, 0.5 mg and 1 mg

**Mumbai, Oct' 30, 2024:** Indoco Remedies Ltd. announced the final approval of the Company's Abbreviated New Drug Application (ANDA) for Varenicline Tablets, 0.5 mg and 1 mg, to market a generic equivalent to the reference listed drug (RLD), Chantix Tablets, 0.5 mg and 1 mg, of PF Prism C.V. (PF) from USFDA.

Varenicline Tablets, 0.5 mg and 1 mg bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Chantix Tablets, 0.5 mg and 1 mg, of PF Prism C.V. (PF).

This product, Varenicline Tablets, 0.5 mg and 1 mg will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa - 403722 in India. Varenicline is used to aid smoking cessation treatment.

Commenting on the achievement, **Ms. Aditi Panandikar, Managing Director** said, "Besides reflecting the capability of Indoco Remedies to deliver products of high-quality standards, this development also provides impetus to our growth aspirations in an important market such as the US."

#### About Indoco Remedies Limited:

Indoco is a fully integrated, research-oriented pharmaceutical company with presence in 55 countries. The Company's turnover is US\$ 200 million with a human capital of 6000 employees, including over 400 skilled scientists and Field Staff who are the strength of the organization.

The Company has 9 manufacturing facilities, 6 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 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 107 million prescriptions annually from over 2,30,000 doctors belonging to various specialties. Indoco has 9 domestic marketing divisions with a strong brand portfolio in various therapeutic segments including Gastro-intestinal, Respiratory, Anti-Infective, Stomatologicals, Ophthalmic, Nutritionals, Cardiovascular, Anti-Diabetics, Pain Management, Gynecology, etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Karvol Plus, ATM, Oxipod, Cital, Sensiform, Sensodent-KF, Cloben-G, Glychek, Kidodent, Carmicide, Rexidin, MCBM 69, Methycal, 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)

For Media Inquiries, please contact:  
Corporate Communications  
Contact No: +91 22 62871000  
E-mail: [corpcom@indoco.com](mailto:corpcom@indoco.com)