Press Release

Granules India Limited Announces ANDA Approval for Trazodone Tablets

Hyderabad, 9 August 2024: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Trazodone Hydrochloride Tablets USP, 50 mg, 100 mg, 150 mg, and 300 mg. It is bioequivalent and therapeutically equivalent to the reference listed drug, Desyrel Tablets, 50 mg, 100 mg, 150 mg, and 300 mg, of Pragma Pharmaceuticals, LLC.

Trazodone tablets are indicated for the treatment of major depressive disorder in adults.

Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India Limited said, "We have received the approval within 10 months of filing the application, which is a testament to our strong R&D capabilities. The product will be launched within this quarter and the market share will grow steadily over the next few quarters."

Granules now has 65 ANDA approvals from the US FDA (64 final approvals and 1 tentative approval).

The current annual U.S. market for Trazodone tablets is approximately $128 Million, according to MAT Jun 2024, IQVIA/IMS Health.

About Granules India Ltd. (BSE: 532482, NSE: GRANULES)

Granules India Limited, incorporated in 1991 is a vertically integrated fast-growing Indian pharmaceutical company headquartered in Hyderabad with best-in-class facilities and a commitment to operational excellence, quality, and customer service. We are among the few pharmaceutical companies in the world to be present in the manufacturing of the entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), and Finished Dosages (FDs). Our products are being distributed to over 300+ customers in regulated and semi-regulated markets with a global presence extending to over 80+ countries with offices across India, U.S., and U.K. The Company has 10 manufacturing facilities out of which 8 are located in India and 2 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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