Press Release ***For Immediate Release***

Granules India Limited Received ANDA Approval for Esomeprazole Magnesium Delayed-Release Capsules

Granules now have a total of 62 ANDA approvals from the US FDA (60 final and 2 tentative approvals)

Esomeprazole Magnesium capsules are used for:

- **Short-term treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD)**
- **Risk reduction of nonsteroidal anti-inflammatory drugs (NSAID)-associated gastric ulcer in adults**
- **Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome**

Hyderabad. October 19, 2023: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg and 40 mg. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Nexium Delayed-Release Capsules, 20 mg and 40 mg, of AstraZeneca Pharmaceuticals LP.

Esomeprazole Magnesium capsules are indicated for short-term treatment of heartburn and other symptoms associated GERD, risk reduction of nonsteroidal anti-inflammatory drugs (NSAID)-associated gastric ulcer in adults at risk for developing gastric ulcers, helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence in combination with amoxicillin and clarithromycin and long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

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The current annual U.S. market for Esomeprazole Magnesium Delayed-Release Capsules is approximately $168 Million, according to MAT Jul 2023, IQVIA/IMS Health.

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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 7 manufacturing facilities out of which 6 are located in India and 1 in the USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL. Get more information https://granulesindia.com

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