



REGISTERED OFFICE

GRANULES INDIA LTD., 2nd Floor, 3rd Block, My Home Hub,
Madhapur, Hyderabad – 500 081, Telangana, INDIA.

Tel: +91 40 69043500, Fax: +91 40 23115145, mail@granulesindia.com, www.granulesindia.com

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Date: October 19, 2023

To,
National Stock Exchange of India Limited
BSE Limited
Symbol: NSE: GRANULES; BSE: 532482

Sub: Press Release

Dear Sir,

We are herewith enclosing the press release given by the Company.

This is for your information and dissemination to the members of the exchange.

Thanking You.

Yours sincerely,

For GRANULES INDIA LIMITED

**CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)**

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.

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

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>

Safe Harbor: This document is to provide general background information about the Company’s activities as at the date of the release. The information contained herein is for general information purposes only and based on estimates and should not be considered as a recommendation that any investor should subscribe / purchase the company shares. The Company makes no representation or warranty, express or implied, as to, and does not accept any responsibility or liability with respect to, the fairness, accuracy, completeness or correctness of any information contained herein. This release may include certain “forward-looking statements”. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, the ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global pharmaceuticals industries, increasing competition, changes in political conditions in India or any other country and changes in the foreign exchange control regulations in India. Neither the company nor its directors and any of the affiliates or employees have any obligation to update or otherwise revise any forward-looking statements. The readers may use their own judgment and are advised to make their own calculations before deciding on any matter based on the information given herein. No part of this release may be reproduced, quoted or circulated without prior written approval from Granules India Limited.

Investor Contacts:

Puneet Varshney General Manager – Finance 9154 3033 98 Puneet.Varshney@granulesindia.com	Chaitanya Tummala Company Secretary 040-69043614 chaitanya.tummala@granulesindia.com
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