



**REGISTERED OFFICE**

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CIN: L24110TG1991PLC012471

**Date: November 08, 2024**

**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** Digitally signed by  
CHAITANYA TUMMALA  
**TUMMALA** Date: 2024.11.08  
11:03:02 +05'30'

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



**Press Release**

**Granules India's Unit V Facility Secures US FDA EIR with 'No Action Indicated' Status**

**Hyderabad, November 8, 2024:** Granules India Limited, a leading pharmaceutical manufacturing company, is pleased to announce that it has received an Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) for its Unit V facility located at Jawaharlal Nehru Pharma City (JNPC), Anakapalli District, Parawada Mandal, Andhra Pradesh. This follows an inspection conducted by the US FDA from April 8 to April 12, 2024.

The US FDA inspection classified the facility as "No Action Indicated" (NAI), indicating compliance with current Good Manufacturing Practices (cGMP) standards and confirming that no further regulatory action is required. This outcome reflects the facility's high standards in the production of Active Pharmaceutical Ingredients (APIs) and Finished Dosages (FDs) for both oncology and non-oncology therapeutic areas.

During the inspection, the FDA conducted a comprehensive Pre-Approval Inspection (PAI) and cGMP audit, which concluded with zero Form 483 observations, underscoring Granules India's commitment to stringent quality control, regulatory compliance, and operational excellence.

*"The successful completion of this US FDA inspection with zero observations and the subsequent receipt of the EIR with NAI status reflects our unwavering commitment to maintaining the highest quality standards in our manufacturing operations,"* said **Dr. Krishna Prasad Chigurupati, Chairman & Managing Director**.

Granules India's Unit V facility plays a pivotal role in the company's mission to deliver high-quality and accessible pharmaceuticals globally by prioritizing regulatory compliance, operational excellence, and value delivery to stakeholders.

The company remains dedicated to producing top-quality pharmaceutical products that meet global health standards.

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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. Amongst the few pharmaceutical companies in the world to be present across the manufacturing of the entire pharmaceutical value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), and Finished Dosages (FDs), Granules products are distributed to over 300+ customers in regulated and semi-regulated markets with a global presence extending to over 80+ countries with offices across India, US and UK. The Company has 10 manufacturing facilities out of which 8 are located in India and 2 are in the USA and has regulatory approvals from the 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 is 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.

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