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

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