

Press Release

Granules India Successfully Completes Two US FDA Audits in a Span of Two Weeks for its Vizag and Jeedimetla facilities with Zero Observations

Zero Observations indicate commitment to comply with best global standards

Hyderabad, 30 June 2023: Granules India Limited, a leading vertically integrated pharmaceutical company has completed the U.S. Food and Drug Administration's (US FDA) Pre-Approval Inspection (PAI) and GMP audit for their Unit IV facility located at Visakhapatnam, Andhra Pradesh, India with zero 483 observations.

Recently, Granules India's Jeedimetla facility located at Telangana, Hyderabad, India also successfully completed the US FDA's surveillance inspection with zero 483 observations.

The Vizag facility was inspected by the US FDA from 26th June to 30th June, 2023 and the Jeedimetla facility from 19th June to 23rd June, 2023. The zero-observation outcome reflects the company's robust quality management systems and commitment to excellence in its operations.

"We are proud of the successful completion of the US FDA surveillance inspections at our Vizag and Jeedimetla facilities with zero observations. This achievement is a testament to our unwavering commitment to quality and compliance. It reinforces our position as a trusted and reliable global pharmaceutical manufacturer." said Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India.

The Unit IV facility located at Visakhapatnam manufactures Active Pharmaceutical Ingredients (API) and the Jeedimetla facility manufactures Active Pharmaceutical Ingredients (API) and Pharmaceutical Formulation Intermediates (PFIs).

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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 7 manufacturing facilities out of which 6 are in India and 1 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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