Press Release

Granules India's Gagillapur Facility Completes US FDA Inspection with Six Observations

- *The Gagillapur facility is responsible for manufacturing Finished Dosages (FDs) and Pharmaceutical Formulation Intermediates (PFIs).*

Hyderabad, September 7, 2024*:* Granules India Limited, announced the completion of the US Food and Drug Administration (USFDA) inspection at its Gagillapur facility in Hyderabad, Telangana. The inspection, conducted from 26th August to 6th September 2024, concluded with six observations.

The recent inspection covered both Current Good Manufacturing Practice (cGMP) and Pre-Approval Inspection (PAI) processes. Granules India is committed to addressing the observations promptly and will submit its response to the USFDA within the stipulated timeframe. The Gagillapur facility continues to play a vital role in the company's global operations, ensuring the supply of high-quality pharmaceutical products to markets worldwide.

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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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