

Press Release

Granules India's Gagillapur facility completes USFDA inspection with eleven observations

Hyderabad, India, October 30, 2026 – Granules India Limited today announced that the United States Food and Drug Administration (USFDA) has concluded a current Good Manufacturing Practice inspection of its finished dosage facility at Gagillapur, Hyderabad. The inspection was conducted from October 19 to October 30, 2026, and concluded with the issuance of a Form FDA 483 containing eleven observations.

This was the first USFDA inspection of the facility since the Warning Letter of February 26, 2025, which followed an inspection in August - September 2024.

None of the observations were related to data integrity or cross-contamination. The observations relate to enhancements in investigations, change control, process and equipment qualification, visual-inspection controls and documentation practices. **There is no impact on manufacturing or distribution of products from the site.** Granules will submit a comprehensive response to the USFDA within the stipulated 15 business days.

Commenting on the inspection, Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, said: "The inspection progressed constructively, and the observations are of a nature that we believe can be fully addressed through our responses and corrective and preventive actions. Quality is the foundation of everything we do at Granules, and we will continue to engage transparently with the agency."

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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 at Hyderabad with best-in-class facilities and 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 entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), Finished Dosages (FDs) and Peptides CDMO. 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, US, Germany, Canada and Switzerland. The Company has 11 manufacturing facilities out of which 8 are in India, 2 in the USA and 1 in Switzerland and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC, and HALAL.

For more information about Granules India Ltd and its initiatives, please visit www.granulesindia.com.

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