

Press Release

Granules Pharmaceuticals, Inc. Receives USFDA EIR for Chantilly Facility

Hyderabad, India, June 3, 2026 – Granules India Limited today announced that its wholly-owned subsidiary, Granules Pharmaceuticals, Inc. (GPI), located in Chantilly, Virginia, US, has received the Establishment Inspection Report (EIR) from the US Food and Drug Administration (FDA), with a Voluntary Action Indicated (VAI) classification.

The inspection was conducted from March 30 to April 3, 2026, during which four Form 483 observations were issued.

This facility plays an important role in Granules' global manufacturing and supply network, with a continued focus on quality systems, regulatory compliance, and patient safety.

Granules remains committed to maintaining the highest standards of quality, safety, and regulatory compliance across its facilities in India and the US.

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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 and Switzerland. The Company has 10 manufacturing facilities out of which 7 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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