

Press Release

Granules India's Unit I Facility Secures US FDA EIR with 'Voluntary Action Indicated' (VAI)

Hyderabad, October 29, 2025: 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 API Unit-I facility located at Bonthapally, Hyderabad. The EIR was issued with an inspection classification of Voluntary Action Indicated (VAI) post the inspection conducted in June 2025.

There was one observation during that inspection, and the Company had submitted its response within the stipulated time.

"The successful completion of this US FDA inspection and the subsequent receipt of the EIR with a satisfactory VAI classification reflects our commitment to maintaining the highest quality standards in our manufacturing operations," said Dr. Krishna Prasad Chigurupati, Chairman & Managing Director.

This facility is one of the world's largest single-site Paracetamol API manufacturing plants by volume. Along with Paracetamol APIs, the Company has established Metformin and Guaifenesin API manufacturing plants in the same facility.

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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