Press Release

Granules Life Sciences Receives First U.S. FDA Approval for Hyderabad Facility

Hyderabad, November 11, 2025: *Granules India Limited* today announced that its wholly owned subsidiary, **Granules Life Sciences Private Limited (GLS)**, located in Hyderabad (FEI: 3030495702), has received **U.S. Food and Drug Administration (FDA)** approval for a product that was the subject of a **Pre-Approval Inspection (PAI)** conducted between **July 28 and August 1, 2025**.

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

With this approval, the GLS facility is now deemed approved by the U.S. FDA, marking a major milestone for Granules India as it expands its finished dosage manufacturing capabilities. This is the first FDA approval for the GLS site.

The company plans to launch the approved product in the U.S. market soon. The same product is already approved and manufactured at Granules' Gagillapur facility. The new approval will help strengthen market share and support business continuity through multi-site manufacturing.

"We plan on launching the product into the U.S. market soon. It is an already approved product at our Gagillapur facility, but we plan on building market share with this approval," said Dr. Krishna Prasad Chigurupati, Chairman & Managing Director, Granules India Limited. "We also have other products filed from this site and expect the U.S. FDA to approve them following necessary audits if required. This marks the first approval from our second Hyderabad facility with finished dosage capabilities."

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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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