

Press Release

Granules Pharmaceuticals Inc. Receives FDA Tentative Approval for Generic Amphetamine Extended-Release Orally Disintegrating Tablets (ADZENYS XR-ODT®)

Hyderabad, December 22, 2025 – Granules Pharmaceuticals Inc., a wholly owned subsidiary of Granules India Limited, has received Tentative Approval (TA) from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Amphetamine Extended-Release Orally Disintegrating Tablets in strengths of 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, and 18.8 mg, the generic equivalent of ADZENYS XR-ODT®. It will be manufactured at Granules' US-based facility located in Chantilly, Virginia.

The product is indicated for the treatment of **Attention Deficit Hyperactivity Disorder (ADHD)** and has an **estimated market size of approximately USD 172 million** according to IQVIA (IMS Health).

Currently, **the market has only one approved generic and one authorized generic**, positioning Granules favourably to expand access to this critical therapy upon launch.

Commenting on the development, the Chairman and Managing Director, Dr. Krishna Prasad Chigurupati, stated: "The tentative approval of this ANDA reaffirms Granules' strategic focus on expanding its portfolio of complex and differentiated generics while strengthening its presence in the central nervous system (CNS) therapeutic area. ADHD is one of the most commonly diagnosed neurodevelopmental disorders in the United States and impacts hundreds of millions of people worldwide. At Granules, we remain committed to improving patient access by delivering high-quality, affordable medications across global markets."

This approval further strengthens Granules' US generics portfolio and underscores its continued investments in complex dosage forms, patient-friendly delivery technologies, and value-driven healthcare solutions.

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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 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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