

Press Release

Granules Pharmaceuticals, Inc. Successfully Completes USFDA Postmarketing Adverse Drug Experience (PADE) Inspection with Zero Observations

Zero Observations indicate a commitment to the highest level of patient safety and product quality

Hyderabad, 4 August 2023: Granules India Limited, announced that Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the company, located in Chantilly, Virginia, USA has successfully completed the United States Food and Drug Administration (USFDA) Post-marketing Adverse Drug Experience (PADE) Inspection for all its entities in the United States, including Granules India Limited. The inspection was closed with zero observations.

The inspection was conducted at Granules Pharmaceuticals Inc. (GPI) from July 31, 2023 to August 03, 2023. This inspection covered the Granules' PADE surveillance, receipts, evaluations, processing and reporting system for the marketed drug products worldwide.

This is Granules India's fourth FDA audit since March with zero observations - a testament to Granules India's unwavering commitment to ensuring the highest level of patient safety and product quality.

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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 8 manufacturing facilities out of which 6 are located in India and 2 are in USA and has regulatory approvals from 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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