

Granules India's Packaging Facility in US gets FDA EIR with No Action Indicated Status

Hyderabad, 5 March 2026: Granules India Limited announced that its US step-down subsidiary, Granules Consumer Health, LLC, a wholly-owned subsidiary of Granules Pharmaceuticals, Inc. has received an Establishment Inspection Report (EIR) with a No Action Indicated (NAI) Status from the US Food and Drug Administration (FDA).

The FDA inspection was conducted at the company's packaging facility in Manassas, Virginia, from December 1 to 3, 2025. This marks the facility's second FDA inspection, following the March 2023 audit, which also concluded with zero observations.

"Granules Consumer Health plays a critical role in our global operations as a packaging and distribution site. We process controlled substances and over-the-counter (OTC) products across three advanced packaging lines. Achieving zero observations in this inspection reflects the strong culture of quality, safety and regulatory excellence demonstrated by our teams," said Dr. Krishna Prasad Chigurupati, Chairman and Managing Director of Granules India.

Granules Consumer Health serves as Granules' front-end division for OTC products in the U.S., leveraging Granules India's manufacturing efficiencies, regulatory compliance, and integrated supply chain. This facility is responsible for packaging both OTC and prescription (Rx) products and serving as a distribution hub for OTC products across 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, Germany, Canada 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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