Press Release *For Immediate Release*

Granules India Limited Confirms USFDA Classification Does Not Impact Ongoing Operations, Assures Commitment to Compliance and Growth

Hyderabad, 4 December 2024: Granules India Limited has confirmed that the U.S. Food & Drug Administration (USFDA) classification of their Gagillapur facility under "Official Action Initiated" (OAI) does not impact the ongoing manufacturing, distribution, or sale of existing products from the site. However, it may impact review of pending submissions from Gagillapur for approval of new products, until the OAI status is resolved.

Granules has undertaken a proactive, voluntary, and comprehensive remediation plan to address the six form 483 observations raised by the USFDA. As part of this effort, we voluntarily paused manufacturing and dispatches in September to conduct a thorough risk assessment, ensuring no product contamination or patient safety concerns. Operations and dispatches have since resumed following this assurance. Our voluntary remediation plan includes robust corrective and preventive actions (CAPAs), oversight by an independent third party, continued product testing for risk assessment, and regular monthly progress updates to the USFDA. To date, over 80% of CAPAs have been completed, with the remainder on track for closure by March 2025. We are now seeking a meeting with the USFDA to present our progress and request a potential reinspection.

Granules' growth trajectory remains robust and diversified, underscoring that our strategy is not solely dependent on new product approvals from the Gagillapur site. Key drivers include new launches from our GPI facility in the US, growth from large-volume products in the US and Europe, capacity addition and commercialization of greenfield formulation facility at Genome Valley, value chain advancements in Europe, and our expanding oncology pipeline from Unit V. These initiatives ensure sustained performance as we work towards resolving the OAI status and reinforcing our commitment to compliance.

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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. We are among the few pharmaceutical companies in the world to be present in the manufacturing of the entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), and Finished Dosages (FDs). 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, U.S., and U.K. The Company has 10 manufacturing facilities out of which 8 are located in India and 2 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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