



NEWS UPDATE

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Granules India to Tighten Oversight After US FDA Warning



Indian drugmaker Granules India is strengthening oversight across its manufacturing facilities after receiving observations from the U.S. Food and Drug Administration. The regulator flagged issues related to record-keeping and contamination control practices at its key plant. In response, the company plans to enhance monitoring systems, digitize documentation, and improve compliance processes to meet global quality standards. Granules, a major global supplier of paracetamol and APIs, derives a significant share of revenue from the U.S. market, making regulatory compliance critical for its business. Experts note that while no immediate regulatory action has been enforced, the move reflects increasing scrutiny of Indian pharma manufacturing quality by global regulators.

Source:

<https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indian-drugmaker-granules-to-tighten-oversight-after-us-fda-warning-exec-says/articleshow/130142104.cms>