



Press Release

For Immediate Release

Granules India Limited Announced ANDA Approval for Colchicine Capsules

Hyderabad, 30 April 2024: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA), filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the Company, for Colchicine Capsules, 0.6 mg. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Mitigare Capsules, 0.6 mg of Hikma International Pharmaceuticals LLC (Hikma).

Colchicine Capsules are indicated for prophylaxis of gout flares in adults.

Granules now have a total of 64 ANDA approvals from the US FDA (63 Final approvals and 1 tentative approvals).

The current annual U.S. market for Colchicine Capsules is approximately \$55 Million, according to MAT Feb 2024, IQVIA/IMS Health.

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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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