

Press Release

For Immediate Release

Granules India Limited Received ANDA Approval for Gabapentin Tablets

Hyderabad, 29 March 2023: Granules India Limited today announced that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Gabapentin Tablets USP, 600 mg and 800 mg.

It is bioequivalent to the reference listed drug product (RLD), Neurontin Tablets, 600 mg and 800 mg, of Viatris Specialty LLC.

The current annual U.S. market for Gabapentin Tablets is approximately \$145 Million, according to MAT Jan 2023, IQVIA/IMS Health.

Gabapentin Tablets are indicated for management of postherpetic neuralgia in adults; and as an adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy.

Granules now has a total of 55 ANDA approvals from US FDA (53 Final approvals and 2 tentative approvals).

Granules India Limited has consistently achieved manufacturing success, set new standards of quality, and expanded its presence across the world.

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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 7 manufacturing facilities out of which 6 are in India and 1 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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