

Press Release

For Immediate Release

Granules India Limited Receives ANDA Approval for Levetiracetam Tablets in record 9 months

Granules now has a total of 56 ANDA final approvals from US FDA

Levetiracetam Tablets are indicated as adjunctive therapy in treatment of partial onset seizures in adults and infants of age 1 month and older children with epilepsy

Hyderabad, 14 Jun 2023: Granules India Limited today announced that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Levetiracetam Tablets USP, 250 mg, 500 mg, 750 mg, and 1,000 mg. bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Keppra Tablets of UCB, Inc. (UCB).

Levetiracetam Tablets are indicated as adjunctive therapy in the treatment of:

- Partial onset seizures in adults and infants of age 1 month and older children with epilepsy;
- Myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy
- Primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.

Granules now has a total of 58 ANDA approvals from US FDA (56 Final approvals and 2 tentative approvals).

The current annual U.S. market for Levetiracetam Tablets is approximately \$247 Million, according to MAT Mar 2023, 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 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) 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 7 manufacturing facilities out of which 6 are located 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. Get more information <https://granulesindia.com>

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