

Press Release

For Immediate Release

Granules India Limited Received ANDA Approval for Losartan and Hydrochlorothiazide Tablets

Granules have a total of 60 ANDA approvals from the US FDA (58 final and 2 tentative approvals)

Losartan potassium and hydrochlorothiazide tablets are indicated for the treatment of:

- **Hypertension to lower blood pressure and**
- **Reduce risk of stroke in patients with hypertension and left ventricular hypertrophy**

Hyderabad. September 30, 2023: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Losartan Potassium and Hydrochlorothiazide Tablets USP, 50 mg/12.5 mg, 100 mg/12.5 mg, and 100 mg/25 mg. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Hyzaar Tablets of Organon LLC.

Losartan potassium and hydrochlorothiazide tablets are indicated for the treatment of hypertension to lower blood pressure and to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy.

Granules now have a total of 60 ANDA approvals from US FDA (58 Final approvals and 2 tentative approvals).

The current annual U.S. market for Losartan and Hydrochlorothiazide Tablets is approximately \$73 Million, according to MAT Jul 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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