Press Release

Granules India Limited Received ANDA Approval for Losartan Potassium Tablets

Hyderabad, 27 February 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 Tablets USP, 25 mg, 50 mg, and 100 mg.

It is bioequivalent to the reference listed drug product (RLD), Cozaar Tablets of Organon LLC. Granules now has a total of 54 ANDA approvals from US FDA (52 Final approvals and 2 tentative approvals).

Losartan potassium tablets are indicated for the treatment of hypertension in adults and pediatric patients 6 years of age and older, to lower blood pressure.

The current annual U.S. market for Losartan potassium Tablets is approximately $336 Million, according to MAT Dec 2022, IQVIA/IMS Health.

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 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 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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