

For Immediate Release

Press Release

Granules India Limited Received ANDA Approval for Metoprolol Succinate ER Tablets

Now Granules has a total of 55 ANDA approvals from US FDA

Hyderabad, 13 Jun 2023: Granules India Limited today, announced that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Metoprolol Succinate Extended-Release Tablets USP, 25 mg, 50 mg, 100 mg and 200 mg. It is bioequivalent to the reference listed drug product (RLD), Toprol-XL Tablets, 25 mg, 50 mg, 100 mg and 200 mg, of Toprol Acquisition LLC.

Metoprolol Succinate ER Tablets are indicated for the treatment of hypertension in order to lower blood pressure.

Granules now has a total of 57 ANDA approvals from US FDA (55 final approvals and 2 tentative approvals).

The current annual U.S. market for Metoprolol Succinate ER Tablets is approximately \$321Million, according to MAT Mar 2023, IQVIA/IMS Health.

END

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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