



Press Release

For Immediate Release

Granules Pharmaceuticals Inc., Receives ANDA Approval for Prazosin Hydrochloride Capsules

Hyderabad, 28 December 2021: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved the Abbreviated New Drug Application (ANDA) filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of Granules India Limited, for Prazosin Hydrochloride Capsules, USP 1mg, 2mg & 5mg. It is bioequivalent to the reference listed drug product (RLD), Mini plus capsules 1Mg, 2Mg & 5 Mg of Pfizer Inc. The product would be available for the US market shortly.

Commenting on the approval **Ms. Priyanka Chigurupati, Executive Director, GPI**, said *“We are pleased to receive the approval of the product and will surely be a valuable addition to our growing product portfolio in the US market.”*

Granules now has a total of 46 ANDA approvals from US FDA (44 Final approvals and 2 tentative approvals).

The current annual U.S. market for Prazosin Hydrochloride 1mg, 2mg, 5mg strengths is approximately \$54 million, according to 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 75+ 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.

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