

*Press Release*

*for Immediate Release*

## **Granules India Limited Received ANDA Approval for Venlafaxine ER Capsules**

**Hyderabad, 19 May 2023:** Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Venlafaxine Hydrochloride Extended-Release Capsules USP, 37.5 mg, 75 mg, and 150 mg. It is bioequivalent to the reference listed drug product (RLD), Effexor XR Extended-Release Capsules of Upjohn US 2 LLC.

Venlafaxine HCl extended-release capsules are indicated for the treatment of: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Social Anxiety Disorder (SAD) and Panic Disorder (PD)

Granules now have a total of 56 ANDA approvals from US FDA (54 Final approvals and 2 tentative approvals).

The current annual U.S. market for Venlafaxine ER Capsules is approximately \$153 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, US, and UK. The Company has 7 manufacturing facilities out of which 6 are in India and 1 in the USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC, and HALAL.

## Safe Harbor

*This document includes certain forward-looking statements. These statements are based on management's current expectations or beliefs and are subject to uncertainty and changes in circumstances. Actual results may vary materially from those expressed or implied by the statements herein due to changes in economic, business, competitive, technological, and/or regulatory factors. Granules India Ltd., its directors, and any of the affiliates or employees are under no obligation to and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events, or otherwise.*

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