



REGISTERED OFFICE

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CIN: L24110TG1991PLC012471

Date: January 24, 2023

To,
National Stock Exchange of India Limited
BSE Limited
Symbol: NSE: GRANULES; BSE: 532482

Sub: Press Release

Dear Sir,

We are herewith enclosing the press release given by the Company.

This is for your information and dissemination to the members of the exchange.

Thanking You.

Yours sincerely,

For GRANULES INDIA LIMITED

CHAITANYA Digitally signed by
TUMMALA CHAITANYA TUMMALA
Date: 2023.01.24
09:10:59 +05'30'

CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)





Press Release

For Immediate Release

Granules Pharmaceuticals Inc., Receives ANDA Approval for Amphetamine Mixed Salts ER Capsules

Hyderabad, 24 January 2023: 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 the company, for Amphetamine Mixed Salts, 5mg, 10mg, 15mg, 20mg, 25mg, and 30mg Extended-Release (ER) capsules. It is bioequivalent to the reference listed drug product (RLD), Adderall XR® Extended-Release capsules of Takeda Pharmaceuticals USA Inc. This product will be manufactured at Granules manufacturing facility in Chantilly, Virginia and is expected to be launched shortly.

Commenting on the approval Ms. Priyanka Chigurupati, Executive Director, GPI, said “*We are pleased to receive the approval of Amphetamine Mixed Salts ER Capsules within 10-months of ANDA filing, which is an Extended-Release dosage form of controlled substance (C-II).*”

Mixed Salts of a Single-Entity Amphetamine ER Capsules are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Granules now have a total of 53 ANDA approvals from US FDA (51 Final approvals and 2 tentative approvals).

The current annual U.S. market for Amphetamine Mixed Salts ER capsule product is approximately \$1.56 Billion, according to MAT Nov 2022, 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.

Safe Harbor: This document is to provide the general background information about the Company's activities as at the date of the release. The information contained herein is for general information purposes only and based on estimates and should not be considered as a recommendation that any investor should subscribe / purchase the company shares. The Company makes no representation or warranty, express or implied, as to, and does not accept any responsibility or liability with respect to, the fairness, accuracy, completeness or correctness of any information contained herein. This release may include certain "forward looking statements". These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global pharmaceuticals industries, increasing competition, changes in political conditions in India or any other country and changes in the foreign exchange control regulations in India. Neither the company, nor its directors and any of the affiliates or employees have any obligation to update or otherwise revise any forward-looking statements. The readers may use their own judgment and are advised to make their own calculations before deciding on any matter based on the information given herein. No part of this release may be reproduced, quoted or circulated without prior written approval from Granules India Limited.

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