



**REGISTERED OFFICE**

**GRANULES INDIA LTD.**, 2nd Floor, 3rd Block, My Home Hub,  
Madhapur, Hyderabad - 500 081, Telangana, INDIA.  
Tel: +91 40 30660000, Fax: +91 40 23115145, mail@granulesindia.com, www.granulesindia.com  
CIN: L24110TG1991PLC012471

**Dated February 11, 2020**

To,  
BSE Limited  
National Stock Exchange of India Limited  
**Symbol: GRANULES Scrip Code: 532482**

Dear Sir,

We are here with enclosing a copy of Press Release issued by the Company for your information and dissemination to the members of the exchange.

Thanking you.

Yours sincerely,

**FOR GRANULES INDIA LIMITED**

*Chaitanya Tummala*  
  
**CHAITANYA TUMMALA**  
**(COMPANY SECRETARY &**  
**COMPLIANCE OFFICER)\***

Encl as above



## ***Press Release***

### **Granules India Limited announces tentative approval of Colchicine Capsules, 0.6 mg, generic equivalent of Mitigare® Capsules, 0.6mg of Hikma International Pharmaceuticals LLC.**

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**Hyderabad, February 11, 2020**

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has tentatively approved the Abbreviated New Drug Application (ANDA) filed by Granules Pharmaceuticals, Inc (GPI), a wholly owned foreign subsidiary of Granules India Limited for Colchicine Capsules, 0.6 mg. It is bioequivalent to the reference listed drug product (RLD), Mitigare Capsules, 0.6 mg, of Hikma International Pharmaceuticals LLC.

**“We are pleased to receive tentative approval for our 4th Paragraph IV ANDA and launch of the product will be as per our agreement with Hikma Pharmaceuticals USA Inc.,”** said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Granules now has a total of 22 ANDA approvals from US FDA (21 Final approvals and 1 tentative approval).

Colchicine capsules are indicated for prophylaxis of gout flares in adults.

**The Mitigare® brand and generic had U.S. sales of approximately \$84 million MAT** for the most recent twelve months ending in December 2019 according to IQVIA Health.

Mitigare® is a registered trademark of Hikma Pharmaceuticals USA Inc.



**About Granules India Ltd. (BSE: 532482, NSE: GRANULES)**

Granules India is a growing pharmaceutical manufacturing company with best in class facilities and is committed to operational excellence, quality and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) which gives the customers flexibility and choice. Granules support customers with unique value, extensive product range, and proactive solutions. The Company's global presence extends to over 250 customers in 60 countries through offices in India, U.S., and U.K. The Company has 6 manufacturing facilities out of which 5 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.

**Contacts:**

Sandip Neogi  
Chief Financial Officer  
040-30663572  
sandip.neogi@granulesindia.com

Chaitanya Tummala  
Company Secretary  
040-30663614  
chaitanya.tummala@granulesindia.com

***Safe Harbour***

*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 employee is 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.*