



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 01, 2021

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 Tummala

**CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)**



Press Release

For Immediate Release

Granules India Limited announces approval of Potassium Chloride Oral Solution USP, generic equivalent of Potassium Chloride Oral Solution of Genus Lifesciences, Inc..

Date: 1st February, 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 Potassium Chloride Oral Solution USP, 20 mEq/15 mL (10%) and 40 mEq/15 mL (20%). It is bioequivalent to the reference listed drug product (RLD), Potassium Chloride Oral Solution, 20 mEq/15 mL (10%) and 40 mEq/15 mL (20%), of Genus Lifesciences, Inc. The product would be available in bottle of 473 ml and is expected to be launched shortly.

“We are pleased to announce approval of first oral liquid product from our growing product portfolio in the US market. This is third approval in the Potassium Chloride product basket reiterating our focussed portfolio strategy.” said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Potassium Chloride is indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction are insufficient.

Granules now has a total of 36 ANDA approvals from US FDA (35 Final approvals and 1 tentative approvals).

Potassium Chloride Oral solution products had U.S. sales of approximately \$75 million for the most recent twelve months ending in November 2020 according to IQVIA Health.



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. Five of these have regulatory approvals from the USFDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

Investor Contacts:

Sandip Neogi

Chief Financial Officer

040-30663563

sandip.neogi@granulesindia.com

Chaitanya Tummala

Company Secretary

040-30663614

chaitanya.tummala@granulesindia.com

Safe Harbor:

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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 employee 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.

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