REGISTERED OFFICE

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CIN: L24110TG1991PLC012471

Dated March 05, 2020

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

Sub: Granules Pharmaceuticals, Inc. received US FDA approval for Potassium Chloride Extended-Release Tablets USP

Ref: Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Dear Sir,

Please be informed 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 Extended-Release Tablets USP, 8 mEq (600 mg) and 10 mEq (750 mg) . It is bioequivalent to the reference listed drug product (RLD), Klor-Con Extended- Release Tablets, 8 mEq (600 mg) and 10 mEq (750 mg), of Upsher-Smith Laboratories, LLC.(Klor-Con® is a trademark of Upsher-Smith Laboratories, LLC.)

Potassium Chloride ER Tablets are used 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 is insufficient.

The Klor-Con® brand and generic had U.S. sales of approximately $54 million MAT for the most recent twelve months ending in December 2019 according to IQVIA Health.

Granules now have a total of 24 ANDA approvals from US FDA (22 Final approvals and 2 tentative approvals).

This is for your information and dissemination to the members

Thanking you.

Yours faithfully

FOR GRANULES INDIA LIMITED

CHAITANYA TUMMALA
COMPANY SECRETARY
COMPLIANCE OFFICER