Press Release ***For Immediate Release***

Granules India Limited announces approval of Potassium Chloride ER Capsules USP, generic equivalent of Micro-K ER Capsules of Nesher Pharmaceuticals (USA) LLC

Date: 17st February, 2021

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Potassium Chloride Extended-Release Capsules USP, 8 mEq (600 mg) and 10 mEq (750 mg). It is bioequivalent to the reference listed drug product (RLD), Micro-K Extended-Release Capsules, 8 mEq and 10 mEq, of Nesher Pharmaceuticals (USA) LLC. The product would be manufactured at our Hyderabad facility and is expected to be launched shortly.

"We are pleased to announce approval of Potassium Chloride Capsule product within first review cycle of 10 months from filing date. This is fourth ANDA approval in our Potassium Chloride product basket." said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Potassium Chloride is indicated for the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxications, and in patients with hypokalemic familial periodic paralysis.It is also indicated for the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop e.g., digitalized patients or patients with significant cardiac arrhythmias, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and certain diarrheal states.

Granules now has a total of 37 ANDA approvals from US FDA (36 Final approvals and 1 tentative approvals).

Potassium Chloride ER Capsule products had U.S. sales of approximately $43 million for the most recent twelve months ending in December 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.

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