



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.

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