



Press Release

For Immediate Release

Granules India Limited announces USFDA approval of Metformin Hydrochloride ER Tablets USP, 500 mg and 1000 mg.

Date: 13th January, 2021

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has granted final approval for its Abbreviated New Drug Application (ANDA) for Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 1000 mg, generic equivalent of Glumetza ER Tablets, 500 mg and 1000 mg, of Bausch Health US LLC (Bausch).

Metformin Hydrochloride ER Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Metformin Hydrochloride ER Tablets had U.S. sales of approximately \$192 million for the most recent twelve months ending in November 2020 according to IQVIA Health.

Granules now has a total of 35 ANDA approvals from US FDA (34 Final approvals and 1 tentative approval).

Glumetza is a trademark of Salix Pharmaceuticals, Inc. or its affiliates.

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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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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