

Press Release

Granules Pharmaceuticals, Inc., a wholly owned subsidiary of Granules India Limited received US FDA approval for generic Methylergonovine tablets

Hyderabad, May 17, 2018: Granules India Ltd., today announced that the US FDA has approved its Abbreviated New Drug Applications (ANDA) for Methylergonovine 0.2 mg Tablets. The ANDA was filed by Granules Pharmaceuticals Inc., a wholly owned subsidiary of Granules India Limited. The approved ANDA is the bioequivalent to the reference listed drug product (RLD), Methergine 0.2 MG.

Methylergonovine is a semi-synthetic ergot alkaloid used for the prevention and control of postpartum haemorrhage.

“Granules Pharmaceuticals Inc., our R&D and manufacturing subsidiary in Virginia was established with an objective to foray into the development and manufacture of products that are niche, on several levels. Our first product approval from this site is a “first generic,” to the market and is a testimony to our objectives and execution capabilities,” said Mr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India Limited.

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 India 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.

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