



Press Release

Granules India Limited announces tentative approval of Guaifenesin ER Tablets, 600 mg and 1200 mg (OTC), generic equivalent of Mucinex® ER Tablets, 600 mg and 1200 mg, of RB Health (US) LLC

Hyderabad, February 13, 2020

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has tentatively approved its Abbreviated New Drug Application (ANDA) for Guaifenesin Extended-Release Tablets, 600 mg and 1200 mg (OTC), generic equivalent of Mucinex® Extended-Release Tablets, 600 mg and 1200 mg, of RB Health (US) LLC.

“Being the only vertically integrated generic player for this product, Guaifenesin ER Tablets is a nice addition to our growing OTC product portfolio in the US market. We look forward to bring this product to market upon patent expiry in April 2020” said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Guaifenesin ER Tablets helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Granules now has a total of 23 ANDA approvals from US FDA (21 Final approvals and 2 tentative approvals).

Mucinex® is a registered trademark of RB Health (US) LLC.



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 and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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