Press Release

Granules India Limited announces approval of Butalbital, Acetaminophen and CaffeineCapsules USP

Hyderabad, April 09, 2020

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 Butalbital, Acetaminophen and Caffeine Capsules USP, 50 mg/300 mg/40 mg. It is bioequivalent to the reference listed drug product (RLD), Butalbital, Acetaminophen and Caffeine Capsules USP, 50 mg/300 mg/40 mg, of Nexgen Pharma, Inc.

Butalbital, Acetaminophen and Caffeine Capsules are used for the relief of the symptom complex of tension (or muscle contraction) headache.

Butalbital, Acetaminophen and Caffeine Capsules USP, 50 mg/300 mg/40 mg had U.S. sales of approximately $42 million MAT for the most recent twelve months ending in February 2020 according to IQVIA Health.

Granules now has a total of 25 ANDA approvals from US FDA (23 Final approvals and 2 tentative approvals).

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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