



Press Release

For Immediate Release

Granules India Limited announces approval of Acetaminophen, Aspirin and Caffeine Tablets (OTC), generic equivalent of Excedrin Migraine Tablets of GlaxoSmithKline Consumer Healthcare

Date: 24th February, 2021

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Acetaminophen, Aspirin and Caffeine Tablets USP, 250 mg/250 mg/65 mg (OTC). It is bioequivalent to the reference listed drug product (RLD), Excedrin Migraine Tablets, 250 mg/250 mg/65 mg, of GlaxoSmithKline Consumer Healthcare. The product would be manufactured at our Hyderabad facility and is expected to be launched shortly.

“We are pleased to announce approval of Acetaminophen, Aspirin and Caffeine Tablets, emphasizing our focus on building sustainable OTC product portfolio in the US market. We received approval for this triple combination product within 14 months from filing. With this, we have received three ANDA approvals over the past month.” said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Acetaminophen, Aspirin and Caffeine Tablets are indicated for the treatment of migraine.

Granules now has a total of 38 ANDA approvals from US FDA (37 Final approvals and 1 tentative approval)

Excedrin is a trademark of GSK Consumer Healthcare S.A.



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.

Investor Contacts:

Sandip Neogi

Chief Financial Officer

040-30663563

sandip.neogi@granulesindia.com

Chaitanya Tummala

Company Secretary

040-30663614

chaitanya.tummala@granulesindia.com

Safe Harbor:

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