



Press Release

For Immediate Release

Granules India Ltd., Issues Voluntary Recall of one batch of Naproxen Sodium 220mg tablets

Hyderabad, 13th September, 2021: Granules India Limited, in a response towards certain media articles announced that Granules USA, Inc., a wholly-owned foreign subsidiary of the Company located in New Jersey, NY, is voluntarily recalling one batch of Naproxen Sodium 220mg tablets at a retail level due to a minor “CGMP deviation”. One batch has 11.4 million units of Naproxen tablets out of which 0.9 million units that were released into the market were recalled. Financially, this does not have a material impact on the Company.

“Granules manufactured and released a batch using Active Pharmaceutical Ingredient (API) from an alternate source prior to the final approval of a filed Prior Approval Supplement. We have since received the authorization to use the API for this ANDA. There was absolutely no harm done at a patient level because the API used in the batch is from an FDA approved source.” said **G. N. Prashanth, Senior Vice President & Head- Corporate Quality Assurance – Granules India Ltd.**

Granules has not received any reports of adverse event that have been confirmed to be directly related to this recall as of the date.

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About Granules India Ltd. (BSE: 532482, NSE: GRANULES)

Granules India Limited, incorporated in 1991 is a vertically integrated fast growing Indian pharmaceutical company headquartered at Hyderabad with best in class facilities and commitment to operational excellence, quality, and customer service. We are among the few pharmaceutical companies in the world to be present in the manufacturing of entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs) and Finished Dosages (FDs). Our products are being distributed to over 300+ customers in regulated and semi-regulated markets with a global presence extending to over 75+ countries with offices across India, U.S. and U.K. The Company has 7 manufacturing facilities out of which 6 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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