



Press Release

For Immediate Release

Granules Pharmaceuticals, Inc. Clears US FDA Audit

Hyderabad, July 21, 2021: Granules India Limited announced that Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the Company located in Chantilly, Virginia, USA had undergone a Pre-Approval Inspection (PAI) audit by the U.S. Food and Drug Administration (FDA) from 21st June 2021 to 25th June 2021. The audit is a pre-approval inspection for three of its applications filed from this facility. The FDA issued two minor observations during the audit.

“The observations were responded to within the stipulated time, and we are happy to inform that the FDA has closed the observations pertaining to this audit with an Establishment Inspection Report on the 20th of July 2021. This is the fifth US FDA audit for this facility” said Ms. Priyanka Chigurupati, Executive Director, GPI.

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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 along with its subsidiaries has a global presence which extends to over 250 customers in over 75 countries through its offices in India, U.S. & U.K. and has seven manufacturing facilities out of which six are located in India and one in the USA. Five out of these seven have regulatory approvals from the USFDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.



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