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Granules India gets US FDA approval for Acetaminophen

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Acetaminophen 650 mg extended release tablets are used primarily for temporary pain management including arthritis relief.

Granules India Ltd has announced that the US FDA has approved its Abbreviated New Drug Application (ANDA) for Acetaminophen 650 mg Tablets, Extended Release, bioequivalent to the reference listed drug product (RLD), Tylenol 650mg tablets, Extended Release.

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“The addition of Acetaminophen 650mg, extended release tablets to our OTC portfolio leverages several components of our value proposition. Granules’ is the only supplier that is backward integrated up to the API on this product. Our vertically integrated approach will enable us to provide a high-quality, cost-efficient product that benefit consumers. With a capacity of over 24,000 mt/year of Acetaminophen API and finished dosage capacity of more than 18 billion units/year, we are confident that we will ensure supply security to our customers which will support us to capture our target market share,” said Mr. Krishna Prasad Chigurupati, Chairman & Managing Director of Granules India.

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 8 manufacturing facilities out of which 6 are located in India, 1 in China and 1 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.