Alembic Pharmaceuticals receives US FDA final approval for Sacubitril, Valsartan tablets

Sacubitril and Valsartan tablets are indicated to reduce the risk of cardiovascular death and hospitalisation for heart failure in adult patients with chronic heart failure. It is also indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in paediatric patients aged one year and older.

Mumbai: Alembic Pharmaceuticals Limited announced that it has received final approval from the US Food & Drug Administration (US FDA) for its abbreviated new drug application (ANDA) for Sacubitril and Valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Entresto Tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, of Novartis Pharmaceuticals Corporation (Novartis).

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