THE ECONOMIC TIMES

Publication : The Economic Times (print)
Date : January 11, 2016
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Reliance Life Sciences Gets US FDA Nod for its Navi Mumbai Plant

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Mumbai: Reliance Life Sciences has received approval from the US drug regulator for its active pharmaceutical ingredient (API) manufacturing facility located at Dhirubhai Ambani Life Sciences Centre in Navi Mumbai.

The biopharmaceutical arm of Mukesh Ambani-led Reliance group has received the approval at a time when Indian generic drug makers are increasingly grappling with regulatory action from the US Food and Drug Administration.

The company manufactures cytotoxic APIs used to make drugs for the treatment of cancer. Last week, it received the Establishment Inspection Report from the US FDA stating its acceptance of the facility and its quality systems for manufacturing and supplying products to the US market, the world's largest pharmaceutical market.

The company says it has consistently made efforts to institute international quality standards

The inspection of the facility was carried out by US FDA investigators in August 2015.

The approval covers two of the later-generation oncology molecules, temozolomide and pemetrexed. Temozolomide is used for the treatment of glioblastoma multiforme, a type of brain tumor. Pemetrexed is used for the treatment of non-small cell lung cancer.

The company said it has consistently made efforts to institute international quality standards covering people, products, processes, facilities, infrastructure and information technology. "It is currently close to being a fully electronic-enabled organisation," a company spokesperson told ET.

The plant, where pharmaceutical API, formulation and biosimilars are manufactured, has already received approval of the European Union. Reliance Life Sciences is a relatively late entrant in the Indian pharmaceutical sector but it leads the industry in marketing plasma proteins.