# Lupin Gets USFDA Nod for Generic Firdapse Tablets, Qualifies for 180-Day Shared Exclusivity




**Mumbai**: Global pharma major Lupin Limited (Lupin) has announced that it has received approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Applications (ANDA) for Amifampridine Tablets, 10 mg.

Amifampridine Tablets, 10 mg, bioequivalent to the reference listed drug (RLD), Firdapse® Tablets, 10 mg, of Catalyst Pharmaceuticals, Inc., for the indication in the approved labeling. Lupin is one of the first ANDA applicants and is eligible for 180 days of shared generic exclusivity.

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with a strong presence across India, the U.S., Other Developed Markets, and Emerging Markets, with products distributed in over 100 markets. Lupin has a diversified portfolio spanning generics, complex generics, specialty medicines, and biosimilars, and continues to strengthen its market position through a differentiated portfolio.

The company maintains strong leadership in the U.S. and India across core therapeutic areas, including cardiovascular, respiratory, diabetes, gastrointestinal, and women's health. 15 state-of-the-art manufacturing facilities support sustainable operations, with 6 research centers and a dedicated workforce of over 26,000 professionals. Lupin continues to expand the healthcare ecosystem through diagnostics, digital health, patient-support programs, and disease management initiatives. Sustainability continues to be a core pillar of the company's business strategy.

**News Source:**

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