

PRESS RELEASE

25th April, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Fingolimod Capsules, 0.5 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Fingolimod Capsules, 0.5 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Gilenya Capsules, 0.5 mg of Novartis Pharmaceuticals Corporation (Novartis). Fingolimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in patients 10 years of age and older. Refer label for a detailed indication.

Fingolimod Capsules, 0.5 mg, have an estimated market size of US\$ 145 million for twelve months ending December 2025 according to IQVIA.

Alembic has a cumulative total of 237 ANDA approvals (219 final approvals and 18 tentative approvals) from USFDA.

About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com;
(Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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