

Alembic Pharma gets USFDA nod for drug to treat influenza A and B in babies

The drug that has received the final approval from the US regulatory body is Oseltamivir Phosphate for Oral Suspension, 6 mg/mL

Alembic has received a cumulative 243 ANDA approvals from the USFDA, comprising 223 final approvals and 20 tentative approvals

Alembic Pharmaceuticals Ltd announced on Friday that it has received final approval from the [US Food and Drug Administration](#) (USFDA) for its Abbreviated New Drug Application (ANDA) for Oseltamivir Phosphate for Oral Suspension, 6 mg/mL.

The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Tamiflu Oral Suspension, 6 mg/mL, of Hoffmann-La Roche.

Oseltamivir Phosphate is an influenza neuraminidase inhibitor (NAI) used for:

- The treatment of acute, uncomplicated influenza A and B in patients aged two weeks and older who have been symptomatic for no more than 48 hours; and
- The prevention of influenza A and B in patients aged one year and older.

According to IQVIA, Oseltamivir Phosphate for Oral Suspension, 6 mg/mL, has an estimated market size of \$27 million for the 12 months ended March 2026.

Alembic has received a cumulative 243 ANDA approvals from the [USFDA](#), comprising 223 final approvals and 20 tentative approvals.

Earlier, on June 19, [Alembic](#) said it received tentative approval from the US health regulator for its generic version of the cancer treatment drug Binimetinib tablets.

The tentative approval from the USFDA is for the ANDA of Binimetinib tablets in the 45 mg strength, the company said in a regulatory filing.

Alembic Pharmaceuticals Q4FY26 performance

Last month, the company reported a 29 per cent rise in consolidated net profit to ₹202.7 crore for the fourth quarter ended March 31, driven by revenue growth across segments.

The company posted a consolidated net profit of ₹156.89 crore in the corresponding period of the previous fiscal year.

Consolidated revenue from operations in the fourth quarter stood at ₹1,847.72 crore, compared with ₹1,769.64 crore a year earlier.

Total expenses during the quarter under review rose to ₹1,730.94 crore from ₹1,591.22 crore in the same period of the previous year.

News Source:

https://www.business-standard.com/industry/news/alembic-pharma-gets-usfda-nod-for-drug-to-treat-influenza-a-and-b-in-babies-126062600304_1.html