PRESS RELEASE

17th October, 2026, Vadodara, India

Alembic Pharmaceuticals Limited receives USFDA Final Approval for Ciprofloxacin and Dexamethasone Otic Suspension USP, 0.3% / 0.1%.

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) for Ciprofloxacin and Dexamethasone Otic Suspension USP, 0.3% / 0.1%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Ciprodex Otic Suspension, 0.3% / 0.1%, of Sandoz Inc. Ciprofloxacin and Dexamethasone Otic suspension is indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in the specific conditions: i) Acute Otitis Media (AOM) in pediatric patients (age 6 months and older) with tympanostomy tubes, and ii) Acute Otitis Externa (AOE) in pediatric (age 6 months and older), adult, and elderly patients. Refer label for a detailed indication.

According to IQVIA, the estimated market size for Ciprofloxacin and Dexamethasone Otic Suspension USP, 0.3% / 0.1%, was US$110 million for twelve months ending June 2026.

Alembic has a cumulative total of 246 ANDA approvals (226 final approvals and 20 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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