

PRESS RELEASE

26th June, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Dapsone Gel, 5%.

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) Dapsone Gel, 5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Aczone Gel, 5%, of Almirall, LLC. Dapsone Gel is indicated for the topical treatment of acne vulgaris. Refer label for a detailed indication.

Alembic has a cumulative total of 244 ANDA approvals (224 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)

For more information, contact:

Ajay Kumar Desai

Phone: +91 22-66953681

Email: ajay.desai@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE: ALEMBIC ROAD, VADODARA - 390 003. • TEL: (0265) 2280550, 2280880 • FAX: (0265) 2281229
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123