PRESS RELEASE

1st December, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Diclofenac Sodium Topical Solution USP, 2% w/w.

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), Diclofenac Sodium Topical Solution USP, 2% w/w. The ANDA was filed by Aleor Dermaceuticals Limited (Aleor) which was amalgamated with Alembic. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Pennsaid Topical Solution, 2% w/w, of Horizon Therapeutics Ireland DAC (Horizon). Diclofenac Sodium Topical Solution is indicated for the treatment of the pain of osteoarthritis of the knee(s). Refer to our label for full indication. Aleor had previously received tentative approval for this ANDA.

Diclofenac Sodium Topical Solution USP, 2% w/w has an estimated market size of US$512 million for twelve months ending Sep 2022 according to IQVIA.

Alembic has received a cumulative total of 177 ANDA approvals (154 final approvals and 23 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 marketing team of over 5000 are well recognized by doctors and patients.

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

For more information contact:

Ajay Kumar Desai Phone: +91 22 - 306 11681 Email: ajay.desai@alembic.co.in	Mitanshu Shah Phone: +91 265 - 6637630 Email: mitanshu.shah@alembic.co.in