

PRESS RELEASE

1st February, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Clarithromycin Tablets USP, 250 mg and 500 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) for Clarithromycin Tablets USP, 250 mg and 500 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Biaxin Filmtab Tablets, 250 mg and 500 mg, of AbbVie Inc. (AbbVie). Clarithromycin Tablets are a macrolide antimicrobial indicated for mild to moderate infections caused by designated, susceptible bacteria in acute bacterial exacerbation of chronic bronchitis in adults; acute maxillary sinusitis; community-acquired pneumonia; pharyngitis/tonsillitis; uncomplicated skin and skin structure infections; acute otitis media in paediatric patients; treatment and prophylaxis of disseminated Mycobacterial infections; Helicobacter pylori infection and duodenal ulcer disease in adults.

Clarithromycin Tablets USP, 250 mg and 500 mg have an estimated market size of US\$ 11 million for twelve months ending September 2021 according to IQVIA.

Alembic has received year to date (YTD) 20 approvals (14 final approvals and 6 tentative approvals) and a cumulative total of 159 ANDA approvals (137 final approvals and 22 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 <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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