17th April, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Carbamazepine Tablets USP, 200 mg

Alembic Pharmaceuticals Limited (Alembic) announced that it has received Final Approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Carbamazepine Tablets USP, 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Tegretol Tablets, 200 mg, of Novartis Pharmaceuticals Corporation. Carbamazepine Tablets USP, 200 mg are indicated for use as an anticonvulsant drug. It is also indicated in the treatment of the pain associated with true trigeminal neuralgia. Refer label for a detailed indication.

Carbamazepine Tablets USP, 200 mg have an estimated market size of US$ 32 million for twelve months ending December 2024 according to IQVIA.

Alembic has a cumulative total of 222 ANDA approvals (196 final approvals and 26 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 5200 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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