Date: 3rd October, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Lamotrigine Extended-Release Tablets USP, 200 mg, 250 mg, and 300 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Lamotrigine Extended-Release Tablets USP, 200 mg, 250 mg, and 300 mg.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

Manisha Saraf
Manisha Saraf
2024.10.03 06:33:15 +05'30'

Manisha Saraf
Company Secretary

Encl.: A/a.

PRESS RELEASE

3rd October, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Lamotrigine Extended-Release Tablets USP, 200 mg, 250 mg, and 300 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) Lamotrigine Extended-Release Tablets USP, 200 mg, 250 mg, and 300 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Lamictal XR Extended-Release Tablets, 200 mg, 250 mg, and 300 mg, of GlaxoSmithKline LLC (GSK). Lamotrigine extended-release tablets are indicated for adjunctive therapy for primary generalized tonic-clonic seizures and partial-onset seizures with or without secondary generalization in patients aged 13 years and older. Also indicated for conversion to monotherapy in patients aged 13 years and older with partial-onset seizures who are receiving treatment with a single antiepileptic drug. Refer label for a detailed indication.

Lamotrigine Extended-Release Tablets USP, 200 mg, 250 mg, and 300 mg have an estimated market size of US$ 163 million for twelve months ending June 2024 according to IQVIA.

Alembic has a cumulative total of 216 ANDA approvals (188 final approvals and 28 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 22-66953681| 7045504460
Email: ajay.desai@alembic.co.in