



Date: 15th January, 2025

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 Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 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 Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 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
Company Secretary
Encl.: A/a.

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

PRESS RELEASE

15th January, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 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) for Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Rexulti Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg, of Otsuka Pharmaceutical Company, Ltd. (Otsuka). Brexpiprazole is an atypical antipsychotic used as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults, and also used in treatment of schizophrenia in adults and pediatric patients ages 13 years and older. Refer label for a detailed indication.

Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg have an estimated market size of **US\$ 2.0 billion** for twelve months ending September 2024 according to IQVIA.

Alembic has a cumulative total of 220 ANDA approvals (194 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)

For more information, contact:

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