



Date: 20th December, 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 Divalproex Sodium Delayed-Release Capsules USP, 125 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 Divalproex Sodium Delayed-Release Capsules USP, 125 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

R. K. Baheti

Director - Finance & CFO

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

20th December, 2024, Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Divalproex Sodium Delayed-Release Capsules USP, 125 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) Divalproex Sodium Delayed-Release Capsules USP, 125 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Depakote Sprinkle Capsules, 125 mg, of AbbVie Inc. Divalproex Sodium is an anti-epileptic drug indicated for monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures; adjunctive therapy in patients with multiple seizure types that include absence seizures. Refer label for a detailed indication.

Divalproex Sodium Delayed-Release Capsules USP, 125 mg have an estimated market size of US\$ 61.1 million for twelve months ending September 2024 according to IQVIA.

Alembic has a cumulative total of 220 ANDA approvals (193 final approvals and 27 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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