Date: 9th September, 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 Limited receives USFDA Final Approval for Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL Single-Dose Prefilled Syringe.

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 Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL Single-Dose Prefilled Syringe.

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
2025.09.09 10:38:05
+05'30'

Manisha Saraf
Company Secretary
Encl.: A/a.

PRESS RELEASE

9th September, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL Single-Dose Prefilled Syringe.

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) Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL Single-Dose Prefilled Syringe. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL, of International Medication Systems Limited (International).

Phytonadione Injectable Emulsion is indicated for the treatment of hypoprothrombinemia due to vitamin K deficiency or interference. It is also indicated for prophylaxis and treatment of vitamin K-deficiency bleeding in neonates. Refer label for a detailed indication.

Phytonadione Injectable Emulsion USP, 1 mg/0.5 mL Single-Dose Prefilled Syringe, have an estimated market size of US$ 44 million for twelve months ending June 2025 according to IQVIA.

Alembic has a cumulative total of 225 ANDA approvals (204 final approvals and 21 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 5500 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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