Date: 07th November, 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 Sumatriptan Injection USP, 4 mg/0.5 mL and 6 mg/0.5 mL, Single-Dose Autoinjector System.

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 Sumatriptan Injection USP, 4 mg/0.5 mL and 6 mg/0.5 mL, Single-Dose Autoinjector System.

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
Digitally signed by Manisha Saraf
Date: 2025.11.07 14:53:59 +05'30'

Manisha Saraf
Company Secretary
Encl.: A/a.

PRESS RELEASE

07th November, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Sumatriptan Injection USP, 4 mg/0.5 mL and 6 mg/0.5 mL, Single-Dose Autoinjector System

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) Sumatriptan Injection USP, 4 mg/0.5 mL and 6 mg/0.5 mL, Single-Dose Autoinjector System. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Imitrex STATdose System, 4 mg/0.5 mL and 6 mg/0.5 mL, of GlaxoSmithKline Intellectual Property Ltd. England. Sumatriptan injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache. Refer label for a detailed indication.

This is Alembic's first drug device combination product. Sumatriptan Injection USP, 4 mg/0.5 mL and 6 mg/0.5 mL, Single-Dose Autoinjector System, have an estimated market size of US$ 73 million for twelve months ending September 2025 according to IQVIA.

Alembic has a cumulative total of 228 ANDA approvals (207 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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