

Date: 24th July, 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 Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 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 Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 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

PRESS RELEASE

24th July, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 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) Fluphenazine Hydrochloride Tablets USP, 1 mg, 2.5 mg, 5 mg, and 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Prolixin Tablets, 1 mg, 2.5 mg, 5mg, and 10 mg, of Apothecon Inc. (Apothecon). Fluphenazine hydrochloride tablets, USP are indicated in the management of manifestations of psychotic disorders. Refer label for a detailed indication.

Alembic has a cumulative total of 210 ANDA approvals (182 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: APL LTD) (BSE: 533573)

For more information contact:
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