



Date: 4th 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 Tentative Approval for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC).

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC).

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

4th December, 2024, Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Tentative Approval for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC)

Alembic Pharmaceuticals Limited (Alembic) announced that it has received Tentative Approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Pataday Once Daily Relief Ophthalmic Solution, 0.7%, of Alcon Laboratories, Inc. (Alcon) NDA - 206276. Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC) is used to temporarily relieve itchy eyes due to pollen, ragweed, grass, animal hair and dander. Refer label for a detailed indication.

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.7% (OTC) has an estimated market size of US\$ 22 million for twelve months ending September 2024 according to IQVIA.

Alembic has a cumulative total of 219 ANDA approvals (192 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:

Ajay Kumar Desai

Phone: +91 22-66953681

Email: ajay.desai@alembic.co.in

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