

Date: 8th March, 2022

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals announces its joint venture, Aleor Dermaceuticals Limited receives USFDA Final Approval for Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 units/gram.

With reference to the captioned subject, this is to inform the exchange that the Company's joint venture, Aleor Dermaceuticals Limited has received US Food and Drug Administration (USFDA) Final Approval for Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 units/gram.

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

Charandeep Singh Saluja Company Secretary

Encl.: A/a.



PRESS RELEASE

8th March, 2022, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 units/gram.

Alembic Pharmaceuticals Limited (Alembic) today announced that its joint venture Aleor Dermaceuticals Limited (Aleor) has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 units/gram. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 U/g/0.1%, of Taro Pharmaceuticals U.S.A. Inc. Nystatin and Triamcinolone Acetonide Ointment is indicated for the treatment of cutaneous candidiasis; it has been demonstrated that the nystatin-steroid combination provides greater benefit than the nystatin component alone during the first few days of treatment.

Nystatin and Triamcinolone Acetonide Ointment has an estimated market size of US\$4 million for twelve months ending Dec 2021 according to IQVIA.

Alembic has received year to date (YTD) 21 approvals (15 final approvals and 6 tentative approvals) and a cumulative total of 160 ANDA approvals (138 final approvals and 22 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 the company can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573).

About Aleor Dermaceuticals Limited

Aleor is a 60:40 joint venture between Alembic and Orbicular Pharmaceutical Technologies Pvt Ltd (Orbicular) formed in Apr'16 focusing on commercialising dermatology products globally.

For more information contact:

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