

Date: 6th September, 2021

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

Dear Sir/Madam,

With, reference to the cantioned 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 Metronidazole Gel USP, 1%.

Please find enclosed herewith our press release

We request you to kindly take the same on record



PRESS RELEASE

6th September, 2021, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Metronidazole Gel USP, 1%.

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 Metronidazole Gel USP, 1%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Metrogel Gel, 1%, of Galderma Laboratories LP (Galderma). Metronidazole Gel USP, 1% is indicated for Indicated for the topical treatment of inflammatory lesions of rosacea. Aleor had previously received tentative approval for this ANDA.

Metronidazole Gel USP, 1% has an estimated market size of US\$ 29 million for twelve months ending June 2021 according to IQVIA.

Alembic has a cumulative total of 149 ANDA approvals (132 final approvals and 17 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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