

Date: 29th July, 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 wholly owned subsidiary, Aleor Dermaceuticals Limited receives USFDA Final Approval for Diclofenac Sodium Topical Gel, 3%.

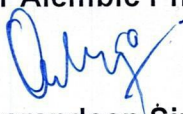
With reference to the captioned subject, this is to inform the exchange that the Company's wholly owned subsidiary, Aleor Dermaceuticals Limited has received US Food and Drug Administration (USFDA) Final Approval for Diclofenac Sodium Topical Gel, 3%.

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.

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229
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PRESS RELEASE

29th July, 2022, Vadodara, India

Alembic Pharmaceuticals announces its wholly owned subsidiary, Aleor Dermaceuticals Limited receives USFDA Final Approval for Diclofenac Sodium Topical Gel, 3%.

Alembic Pharmaceuticals Limited (Alembic) today announced that its wholly owned subsidiary, Aleor Dermaceuticals Limited (Aleor) has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Diclofenac Sodium Topical Gel, 3%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Solaraze Topical Gel, 3%, of Fougera Pharmaceuticals Inc. (Fougera). Diclofenac Sodium Topical Gel, 3% is indicated for the topical treatment of actinic keratoses. Sun avoidance is indicated during therapy.

Diclofenac Sodium Topical Gel, 3% has an estimated market size of US\$10 million for twelve months ending Mar., 2022 according to IQVIA.

Alembic has received a cumulative total of 169 ANDA approvals (145 final approvals and 24 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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