

## PRESS RELEASE

29<sup>th</sup> 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: APLLTD) (BSE: 533573).

For more information contact:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 6637630
Email: <a href="mailto:ajay.desai@alembic.co.in">ajay.desai@alembic.co.in</a>	Email: <a href="mailto:mitanshu.shah@alembic.co.in">mitanshu.shah@alembic.co.in</a>



### **ALEMBIC PHARMACEUTICALS LIMITED**

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880. • FAX : (0265) 2281229  
website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123