

**PRESS RELEASE**

27<sup>th</sup> November, 2018, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Approval for Temazepam Capsules USP 7.5mg, 15mg, 22.5mg and 40mg.**

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Temazepam Capsules USP 7.5mg, 15mg, 22.5mg and 40mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Restoril Capsules, 7.5mg, 15mg, 22.5mg and 40mg, of SpecGx LLC. Temazepam Capsules are indicated for short term treatment of insomnia.

Temazepam Capsules USP 7.5mg, 15mg, 22.5mg and 40mg have an estimated market size of US\$ 48 million for twelve months ending December 2017 according to IQVIA.

Alembic has a cumulative total of 80 ANDA approvals (67 final approvals and 13 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: APL LTD) (BSE: 533573)

For more information contact:

|   |   |
|---|---|
| Ajay Kumar Desai  | Mitanshu Shah   |
| Phone: +91 22 - 306 11681   | Phone: +91 265 - 3007630  |
| 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**