Alembic
Touching Lives over 100 years

Date: 15th January, 2020

To,
The Manager,
Listing Department
National Stock Exchange of India Ltd.
'Exchange Plaza'
Bandra Kurla Complex, Bandra (E),
Mumbai – 400 051

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Tizanidine Hydrochloride Capsules, 2 mg, 4 mg, and 6 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Tizanidine Hydrochloride Capsules, 2 mg, 4 mg, and 6 mg.

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

Authorised Signatory

Encl.: A/a.

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PRESS RELEASE

15th January, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Tizanidine Hydrochloride Capsules, 2 mg, 4 mg, and 6 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that the Company has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Tizanidine Hydrochloride Capsules, 2 mg, 4 mg, and 6 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Zanaflex Capsules, 2 mg, 4 mg, and 6 mg, of Covis Pharma B.V. Tizanidine hydrochloride is a central alpha-2-adrenergic agonist indicated for the management of spasticity. Because of the short duration of therapeutic effect, treatment with tizanidine hydrochloride capsules should be reserved for those daily activities and times when relief of spasticity is most important.

Tizanidine Hydrochloride Capsules, 2 mg, 4 mg, and 6 mg have an estimated market size of US$ 28 million for twelve months ending September 2019 according to IQVIA.

Alembic has a cumulative total of 111 ANDA approvals (99 final approvals and 12 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 http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE:APLLTD) (BSE:533573)

For more information contact:

Ajay Kumar Desai Phone: +91 22 - 306 11681 Email: ajay.desai@alembic.co.in	Mitanshu Shah Phone: +91 265 - 3007630 Email: mitanshu.shah@alembic.co.in

ALEMBIC PHARMACEUTICALS LIMITED VADODARA 390 003