Date: 23rd April, 2021

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

Dear Sir/Madam,

**Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg and 100 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 Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg and 100 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**

**Charandeep Singh Saluja**
**Company Secretary**

Encl.: A/a.

**PRESS RELEASE**

23rd April, 2021, Vadodara, India

## Alembic Pharmaceuticals announces USFDA Final Approval for Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg and 100 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg and 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Sinequan Capsules 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg, of Pfizer Inc. (Pfizer). Doxepin Hydrochloride Capsules are recommended for the treatment of: i) Psychoneurotic patients with depression and/or anxiety, ii) Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol), iii) Depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly), iv) Psychotic depressive disorders with associated anxiety including involutional depression and manic-depressive disorders.

Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg have an estimated market size of US$ 41 million for twelve months ending December 2020 according to IQVIA.

Alembic has a cumulative total of 141 ANDA approvals (124 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 Alembic can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:


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