

Date: 23<sup>rd</sup> July, 2019

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 Tentative Approval for Dapagliflozin Tablets, 5 mg and 10 mg.**

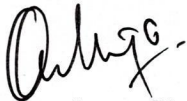
With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Dapagliflozin Tablets, 5 mg and 10 mg.

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.

**ALEMBIC PHARMACEUTICALS LIMITED**

**PRESS RELEASE**

23<sup>rd</sup> July 2019, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Dapagliflozin Tablets, 5 mg and 10 mg.**

Alembic Pharmaceuticals Limited today announced that the Company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Dapagliflozin Tablets, 5 mg and 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD) Farxiga Tablets, 5 mg and 10 mg; of AstraZeneca AB (AstraZeneca). Dapagliflozin Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dapagliflozin Tablets have an estimated market size of US\$ 1.7 billion for twelve months ending December 2018 according to IQVIA.

Alembic now have a total of 99 ANDA approvals (88 final approvals and 11 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:

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**ALEMBIC PHARMACEUTICALS LIMITED**