

Date: 21<sup>st</sup> October, 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 Fenofibrate Capsules USP, 67 mg, 134 mg and 200 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 Fenofibrate Capsules USP, 67 mg, 134 mg and 200 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

21<sup>st</sup> October, 2020, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Final Approval for Fenofibrate Capsules USP, 67 mg, 134 mg and 200 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) Fenofibrate Capsules USP, 67 mg, 134 mg and 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Tricor Micronized Capsules, 67 mg, 134 mg and 200 mg, of AbbVie Inc. (AbbVie). Fenofibrate Capsules are indicated as adjunctive therapy to diet for the reduction of LDL-C, Total-C, Triglycerides and Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb). Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and non-pharmacological interventions alone has been inadequate. Fenofibrate capsules are also indicated as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson Types IV and V hyperlipidemia).

Fenofibrate Capsules USP, 67 mg, 134 mg and 200 mg have an estimated market size of US\$ 17 million for twelve months ending June 2020 according to IQVIA.

Alembic has a cumulative total of 133 ANDA approvals (115 final approvals and 18 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)

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**ALEMBIC PHARMACEUTICALS LIMITED**

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