

Date: 6th January, 2022

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 Entacapone Tablets USP, 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 Entacapone Tablets USP, 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.

PRESS RELEASE

6th January, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Entacapone Tablets USP, 200 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Entacapone Tablets USP, 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Comtan Tablets, 200 mg, of Orion Corporation. Entacapone Tablets are indicated as an adjunct to levodopa and carbidopa to treat end-of-dose "wearing-off" in patients with Parkinson's disease.

Entacapone Tablets USP, 200 mg have an estimated market size of US\$ 10.5 million for twelve months ending September 2021 according to IQVIA.

Alembic has received year to date (YTD) 17 approvals (13 final approvals and 4 tentative approvals) and a cumulative total of 156 ANDA approvals (136 final approvals and 20 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	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 6637630
Email: ajay.desai@alembic.co.in	Email: mitanshu.shah@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229
website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123