

PRESS RELEASE

1st July, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Nitrofurantoin Capsules, USP (Macrocrystals), 25 mg, 50 mg and 100 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 Nitrofurantoin Capsules, USP (Macrocrystals), 25 mg, 50 mg and 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Macrochantin Capsules, 25 mg, 50 mg, and 100 mg, of Alvogen Malta Operations Ltd. Nitrofurantoin capsules, USP (Macrocrystals) is specifically indicated for the treatment of urinary tract infections when due to susceptible strains of Escherichia coli, enterococci, Staphylococcus aureus, and certain susceptible strains of Klebsiella and Enterobacter species.

Nitrofurantoin Capsules, USP (Macrocrystals), 25 mg, 50 mg and 100 mg have an estimated market size of US\$ 23 million for twelve months ending March 2021 according to IQVIA.

Alembic has a cumulative total of 146 ANDA approvals (128 final approvals and 18 tentative approvals) from USFDA.

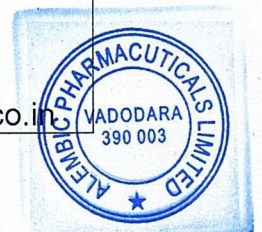
About Alembic Pharmaceuticals Limited

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)

For more information contact:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 3007630
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