

**PRESS RELEASE**

22<sup>nd</sup> May, 2026 Vadodara, India

**Alembic Pharmaceuticals Limited announces USFDA Final Approval for Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg and 300 mcg.**

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) Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg and 300 mcg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Synthroid Tablets, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg and 300 mcg, of AbbVie, Inc. (AbbVie). Levothyroxine sodium tablets are indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Levothyroxine sodium tablets are indicated as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer. Refer label for a detailed indication.

Levothyroxine Sodium Tablets USP have an estimated market size of US\$ 1,869 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 239 ANDA approvals (220 final approvals and 19 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 field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com); (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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