

PRESS RELEASE

1st November, 2022, Vadodara, India

Alembic Pharmaceuticals announces its first injectable product approval from its General Sterile Facility - Final Approval for Glycopyrrolate Injection USP.

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 Glycopyrrolate Injection USP, 0.2 mg/1 mL and 0.4 mg/2 mL (0.2 mg/mL) Single-dose Vials and 1 mg/5 mL (0.2 mg/mL) and 4 mg/20 mL (0.2 mg/mL) Multiple-dose Vials.

This is the first injectable product approval from our General Sterile Facility (F-3) which was inspected in August, 2022.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), of Hikma Pharmaceuticals USA Inc. (Hikma). Glycopyrrolate Injection is indicated for use as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation. When indicated, Glycopyrrolate Injection may be used intraoperatively to counteract surgically or drug-induced or vagal reflexes associated arrhythmias. Glycopyrrolate protects against the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) of cholinergic agents such as neostigmine and pyridostigmine given to reverse the neuromuscular blockade due to non-depolarizing muscle relaxants. It is also indicated for use in adults as adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or when oral medication is not tolerated.

Glycopyrrolate Injection USP, has an estimated market size of US\$ 42 million for twelve months ending June 2022 according to IQVIA.

Alembic has a cumulative total of 173 ANDA approvals (149 final approvals and 24 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.

ALEMBIC PHARMACEUTICALS LIMITED



Information about Alembic can be found at <https://www.alembicpharmaceuticals.com/>;
(Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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