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Orit Labs receives USFDA approval for peptic ulcer therapy

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The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Robinul and Robinul Forte Tablets, 1 mg and 2 mg, of Casper Pharma LLC (Casper Pharma).

Alembic Pharmaceuticals Limited recently announced its wholly owned subsidiary Orit Laboratories LLC has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Glycopyrrolate Tablets USP, 1 mg and 2 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Robinul and Robinul Forte Tablets, 1 mg and 2 mg, of Casper Pharma LLC (Casper Pharma). Glycopyrrolate Tablets are indicated for use as adjunctive therapy in the treatment of peptic ulcer.

Glycopyrrolate Tablets USP, 1 mg and 2 mg have an estimated market size of $ 15 million for twelve months ending December 2017 according to IQVIA. Alembic has a cumulative total of 81 ANDA approvals (68 final approvals and 13 tentative approvals) from USFDA.