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Alembic Pharma receives US FDA approval for depression drugs

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Desipramine Hydrochloride tablets are available in USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg



Alembic Pharmaceuticals has received final approval from the US Food & Drug Administration (US FDA) for its Abbreviated New Drug Application (ANDA) for Desipramine Hydrochloride tablets USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Norpramin Tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg, of Validus Pharmaceuticals LLC. Desipramine Hydrochloride Tablets, USP are indicated for the treatment of depression.

Desipramine Hydrochloride tablets USP, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg have an estimated market size of $ 7 million for twelve months ending March 2021 according to IQVIA.

Alembic has a cumulative total of 147 ANDA approvals (129 final approvals and 18 tentative approvals) from US FDA.