

Alembic Pharma bags US FDA approval for OCD caps

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Clomipramine Hydrochloride Capsules are available in the strengths of 25 mg, 50 mg and 75 mg



Alembic Pharmaceuticals has received final approval from the US Food & Drug Administration (US FDA) for its Abbreviated New Drug Application (ANDA) for Clomipramine Hydrochloride Capsules USP, 25 mg, 50 mg, and 75 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Anafranil Capsules, 25 mg, 50 mg, and 75 mg, of SpecGX LLC. Clomipramine Hydrochloride Capsules are indicated for the treatment of obsessions and compulsions in patients with Obsessive-Compulsive Disorder (OCD).

Clomipramine Hydrochloride Capsules USP, 25 mg, 50 mg, and 75 mg, have an estimated market size of \$32 million for twelve months ending June 2021 according to IQVIA.

Alembic has a cumulative total of 149 ANDA approvals (131 final approvals and 18 tentative approvals) from the US FDA.