Alembic Pharma gets USFDA nod for generic medication

The approved ANDA is therapeutically equivalent to GlaxoSmithKline LLC's Lamictal XR extended-release tablets in strength of 200 mg, 250 mg, and 300 mg, it added.

New Delhi: Alembic Pharmaceuticals on Thursday said it has received approval from the US health regulator to market a generic medication for seizures. The company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Lamotrigine extended-release tablets (USP 200 mg, 250 mg, and 300 mg), the drug firm said in a regulatory filing.

The approved ANDA is therapeutically equivalent to GlaxoSmithKline LLC's Lamictal XR extended-release tablets in strength of 200 mg, 250 mg, and 300 mg, it added.

Lamotrigine extended-release tablets are indicated for adjunctive therapy for primary generalised tonic-clonic seizures and partial-onset seizures with or without secondary generalisation in patients aged 13 years and older.

The drug is also indicated for conversion to monotherapy in patients aged 13 years and older with partial-onset seizures who are receiving treatment with a single antiepileptic drug.

According to IQVIA, Lamotrigine Extended-Release Tablets (200 mg, 250 mg, and 300 mg) have an estimated market size of USD 163 million for twelve months ending June 2024.

The company said it now has a cumulative total of 216 ANDA approvals from the USFDA.

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