Zydus receives final approval from USFDA for Dapagliflozin Tablets, 5 mg and 10 mg

Ahmedabad, India, 8 April, 2026

Zydus Lifesciences Limited ("Zydus") has received final approval from the United States Food and Drug Administration (USFDA) for Dapagliflozin Tablets, 5 mg and 10 mg (USRLD: Farxiga® Tablets, 5 mg and 10 mg).

Dapagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. With this approval, Zydus is eligible for 180 days of shared generic drug exclusivity for Dapagliflozin Tablets, 5 mg and 10 mg.

Dapagliflozin tablets will be manufactured at the group's formulation manufacturing facility at SEZ, Ahmedabad. Dapagliflozin tablets had annual sales of USD 10.2bn in the United States (IQVIA MAT February 2026).

The group now has 436 approvals and has so far filed 505* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31-Dec-2025)*

PRESS RELEASE

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