

Zydus receives final approval from USFDA for Theophylline Extended-Release Tablets, 300 mg and 450 mg

Ahmedabad, India, 22 May, 2024

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) to market Theophylline Extended-Release Tablets, 300 mg and 450 mg (USRLD: Theo-Dur Extended-Release Tablets).

Theophylline is used to treat asthma and chronic obstructive pulmonary disease (COPD). The drug will be manufactured at the group’s formulation manufacturing facility in Ahmedabad SEZ, India.

Theophylline Extended-Release Tablets, 300 mg and 450 mg had annual sales of USD 12.6 mn in the United States (IQVIA MAT March 24).

The group now has 396 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st March 2024)*



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