Zydus receives final approval from the USFDA for Oxcarbazepine Tablets USP, 150 mg, 300 mg and 600 mg

Ahmedabad, India, 4 July, 2023

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) for Oxcarbazepine Tablets USP, 150 mg, 300 mg and 600 mg (USRLD: Trileptal® Tablets, 150 mg, 300 mg, and 600 mg).

Oxcarbazepine is used alone or with other medications to treat seizure disorders (epilepsy). The product will be manufactured at the group's formulation manufacturing facility in Baddi, Himachal Pradesh (India).

Oxcarbazepine Tablets USP, 150 mg, 300 mg and 600 mg had annual sales of USD 105 mn in the United States (IQVIA MAT May 2023).

The group now has 374 approvals and has so far filed over 442* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st March 2023)

PRESS RELEASE

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