Zydus receives Final Approval from the USFDA for Doxepin Hydrochloride Capsules

Ahmedabad, India, 28 March, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereinafter referred to as "Zydus") has received final approval for Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg (USRLD: Sinequan® Capsules) from the United States Food and Drug Administration (USFDA).

Doxepin Hydrochloride capsule is recommended for the treatment of Psychoneurotic patients with depression and/or anxiety, Depression and/or anxiety associated with alcoholism and organic disease, and Psychotic depressive disorders with associated anxiety including involutional depression and manic-depressive disorders. The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg had annual sales of USD 28.9 mn in the United States (IQVIA MAT Jan. 2023).

The group now has 355 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)

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PRESS RELEASE

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