Zydus receives final Approval from the USFDA for Doxepin Hydrochloride Capsules USP, 150 mg

Ahmedabad, India, 24 March, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereinafter referred to as "Zydus") has received final approval for Doxepin Hydrochloride Capsules USP, 150 mg (USRLD: Sinequan® Capsules) from the United States Food and Drug Administration (USFDA).

Doxepin Hydrochloride capsule is indicated to treat mental/mood problems such as depression and anxiety. It helps improve moods and feelings of well-being, relieves anxiety and tension, helps sleep better and increases the energy level. The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Doxepin Hydrochloride Capsules USP, 150 mg had annual sales of USD 2.11 mn in the United States (IQVIA MAT Jan. 2023).

The group now has 353 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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