Zydus receives Final Approval from the USFDA for Loperamide Hydrochloride Capsules USP, 2 mg

Ahmedabad, India, 28 March, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereinafter referred to as "Zydus") has received final approval for Loperamide Hydrochloride Capsules USP, 2 mg (USRLD: Imodium® Capsules) from the United States Food and Drug Administration (USFDA).

Loperamide hydrochloride capsule is indicated for the control and symptomatic relief of acute nonspecific diarrhea and chronic diarrhea associated with inflammatory bowel disease. The drug will be manufactured at the group's formulation manufacturing facility at SEZ, Ahmedabad (India).

Loperamide Hydrochloride Capsules USP, 2 mg had annual sales of USD 34.7 mn in the United States (IQVIA MAT, January 2023).

The group now has 356 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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