

Zydus receives final approvals from USFDA for Ivermectin Tablets USP, 3 mg and Dapsone Tablets USP, 25 mg and 100 mg

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Zydus Lifesciences Limited., (hereafter referred to as “Zydus”) has received final approvals from the United States Food and Drug Administration (USFDA) for Ivermectin Tablets USP, 3 mg (USRLD: Stromectol® Tablets, 3 mg) and Dapsone Tablets USP, 25 mg and 100 mg (USRLD: Dapsone Tablets USP, 25 mg and 100 mg).

Ivermectin Tablets USP, 3 mg, are prescription anti-parasitic medications primarily indicated for treating parasitic worm infections in humans, specifically intestinal strongyloidiasis and onchocerciasis. Ivermectin tablets will be manufactured at the group’s formulation manufacturing facility at SEZ, Ahmedabad and distributed by Viona Pharmaceuticals Inc. Ivermectin Tablets USP, 3 mg had annual sales of USD 14.8 mn

Dapsone Tablets USP, 25 mg and 100 mg are indicated for the treatment of leprosy (all forms, including multibacillary and paucibacillary) and dermatitis herpetiformis. It acts as an anti-infective and antibacterial agent and is used to control skin lesions in dermatitis herpetiformis and for leprosy. Dapsone tablets will be manufactured at the group’s formulation manufacturing facility at SEZ-II, Ahmedabad and distributed by Viona Pharmaceuticals Inc. Dapsone Tablets USP, 25 mg and 100 mg had annual sales of USD 8.4 mn in the United States (IQVIA MAT December 2025).

The group now has 434 approvals and has so far filed 505* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31-Dec-2025)*



**PRESS
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