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Orit Lab gets USFDA nod for Fenofibrate Tablets

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The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Tricor Tablets, 54 mg and 160 mg, of AbbVie Inc.

Alembic Pharmaceuticals Limited (Alembic) has announced that its wholly owned step down subsidiary Orit Laboratories LLC has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Fenofibrate Tablets USP, 54 mg and 160 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Tricor Tablets, 54 mg and 160 mg, of AbbVie Inc. (AbbVie). Fenofibrate Tablets USP, 54 mg and 160 mg are indicated as an adjunct to diet to reduce elevated LDL-C, Total-C, TG and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidaemia and for treatment of adult patients with severe hypertriglyceridemia.

Fenofibrate Tablets USP, 54 mg and 160 mg have an estimated market size of US$ 92 million for twelve months ending December 2018 according to IQVIA. Alembic has a cumulative total of 85 ANDA approvals (72 final approvals and 13 tentative approvals) from USFDA.