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Alembic pharma receives USFDA approval for two new drugs

13 August 2019 | News | By Manbeena Chawla

Drugs for lowering cholesterol and treating elevated intraocular pressure

Gujarat based Alembic Pharmaceuticals Limited has announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Fenofibrate Tablets USP, 48 mg and 145 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Tricor Tablets, 48 mg and 145 mg, of AbbVie Inc. (AbbVie). Fenofibrate Tablets, USP are indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), Triglycerides and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDLC) in adult patients with primary hypercholesterolernla or mixed dyslipidemia.

It is also indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia. Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually obviate the need for pharmacologic intervention. Markedly elevated levels of serum triglycerides (e.g. > 2,000 mg/dl) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied.

The company has also announced approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dorzolamide Hydrochloride Ophthalmic Solution USP, 2%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Trusopt Ophthalmic Solution, 2%, of Merck Sharp & Dohme Corp. Dorzolamide Hydrochloride Ophthalmic Solution is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.