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USFDA approves Aurobindo Pharma’s Azithromycin to treat infections

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The company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Azithromycin Oral suspension 100 mg /5 mL and 200 mg/5 mL.

Drug firm Aurobindo Pharma received a final nod from the US health regulator for its Azithromycin Oral suspension used for the treatment of infections.

The company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Azithromycin Oral suspension 100 mg /5 mL and 200 mg/5 mL.

The product is a generic version of Pfizer Inc's Zithromax oral suspension.

"The product will be launched in November 2018," Aurobindo Pharma said.

Azithromycin oral suspension is indicated for the treatment of patients with mild to moderate infections, it added.

According to IQVIA, the approved product has an estimated market size of $ 71 million for the 12 months ending August 2018.

The company now has a total of 386 abbreviated new drug application (ANDA) approvals (357 final approvals including 19 from Aurolife Pharma LLC and 29 tentative approvals) from the USFDA, it added.

Aurobindo Pharma manufactures generic pharmaceuticals and active pharmaceutical ingredients. The company's product portfolio is spread over major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, Anti-Allergies and Anti-Diabetics.

Shares of Aurobindo Pharma were trading at Rs 773.75 per scrip on the BSE, down by 0.58 per cent from its previous close.

On the BSE, 86,000 shares were traded in the counter so far compared with average daily volumes of 1.89 lakh shares in the past two weeks

On a consolidated basis, Aurobindo Pharma's net profit fell 12.12% to Rs 455.66 crore on 15.48% increase in net sales to Rs

4181.56 crore in Q1 June 2018 over Q1 June 2017.