

Aurobindo Pharma gets FDA approval for diabetes drug

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Bangalore: India-based Aurobindo Pharma has received tentative approval from the US Food & Drug Administration for pioglitazone hydrochloride and metformin hydrochloride Tablets, 15mg (base)/500mg and 15mg (base)/850mg. The product will be eligible for final approval upon the expiration of 180-day generic drug exclusivity.

Pioglitazone hydrochloride and metformin hydrochloride tablets are the generic equivalent of Takeda Global Research Development Center's Actoplus Met Tablets. The tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both pioglitazone and metformin is appropriate. The product has a market size of approximately \$433 million for the 12 months ending March 2012 according to IMS.

The product has been approved out of Unit VII (SEZ) formulations facility in Hyderabad, India.