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Aurobindo's new generic wins FDA approval

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Aurobindo Pharma has announced that the company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Norethindrone Acetate Tablets USP, 5mg.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Aygestin Tablets, 5 mg, of Duramed Pharmaceuticals.

Norethindrone Acetate Tablet is used in the treatment of endometriosis, uterine bleeding caused by abnormal hormone levels, and secondary amenorrhea. The approved product has an estimated market size of $24 million for the twelve months ending November 2015 according to IMS.

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