BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Lupin gets FDA nod for generic Ortho Tri-cyclen Lo Tablets

July 5, 2012 | Regulatory | By BioSpectrum Bureau

Lupin gets FDA nod for generic Ortho Tri-cyclen Lo Tablets



Mumbai: Mumbai-based pharma major Lupin's subsidiary, Lupin Pharmaceuticals, has received approval for its Norgestimate and Ethinyl Estradiol Tablets, 0.18 mg/0.025 mg, 0.215 mg/0.025 mg, and 0.25 mg/0.025 mg, from the US Food and Drugs Administration (FDA).

Lupin's Norgestimate and Ethinyl Estradiol Tablets are the AB-rated generic equivalent of Ortho Tri-cyclen Lo Tablets,0.18 mg/0.025 mg, 0.215 mg/0.025 mg, and 0.25 mg/0.025 mg, of Janssen Pharmaceuticals. Norgestimate and Ethinyl Estradiol Tablets are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

Ortho Tri-cyclen Lo Tablets had annual US sales of approximately $421 million for the twelve months ending March 2012, according to IMS Health sales data.