

Sun Pharma bags FDA approval for generic Crestor

21 July 2016 | News | By BioSpectrum Bureau

Sun Pharma bags FDA approval for generic Crestor



Sun Pharma has announced that one of its subsidiaries has received final approval from US FDA for its Abbreviated New Drug Application (ANDA) for generic version of Crestor, Rosuvastatin Calcium tablets 5 mg (base), 10mg (base), 20 mg (base) and 40 mg (base).

These Rosuvastatin Calcium tablets are therapeutic equivalents of IPR Pharmaceuticals, Inc.'s Crestor tablets. As per IMS MAT May 2016, these tablets have annual sales of approximately \$6.8 billion in the US.

These tablets are indicated for the treatment of adult patients with Hypertriglyceridemia, Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia) and adult patients with Homozygous Familial Hypercholesterolemia.