BioSpectrum the business of Bio & Health Sciences

Aurobindo Pharma receives FDA approval for Polymyxin B for Injection

06 April 2016 | News | By BioSpectrum Bureau

Aurobindo Pharma receives FDA approval for Polymyxin B for Injection

Aurobindo Pharma is pleased to announce that the company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Polymyxin B for Injection USP, 500,000 units/vial. This product is expected to be launched in Q2 FY16-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Polymyxin B for Injection USP, 500,000 units/vial of Eurohealth International Sarl.

Polymyxin B for Injection is an Anti-Infective used in the treatment of infections of the urinary tract, meninges, bloodstream and eye caused by susceptible strains of Pseudomonas aeruginosa. The approved product has an estimated market size of $ 7.6 million for the twelve months ending February 2016 according to IMS.