BioSpectrum the business of Bio & Health Sciences

# Aurobindo Pharma receives FDA approval for Isosulfan blue injection

05 February 2016 | News | By BioSpectrum Bureau

**Aurobindo Pharma receives FDA approval for Isosulfan Blue injection**

Aurobindo Pharma has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Isosulfan Blue Injection, 1 percent (50 mg/5 mL) single-dose vials. The product is expected to be launched in Q4 FY15-16.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) LymphazurinTM Injection, 1 percent, of Covidien. Isosulfan Blue Injection under Cardio Vascular therapeutic group, is used in a lymphography procedure.

Isosulfan Blue Injection upon subcutaneous administration, delineates the lymphatic vessels draining the region of injection. The approved product has an estimated market size of $57 million for the twelve months ending December 2015 according to IMS.