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FDA nod for Esmolol Hydrochloride Injection

28 July 2015 | News | By BioSpectrum Bureau

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Aurobindo Pharma has announced that the company has received final approvals from the US Food and Drug Administration (USFDA) to manufacture and market Esmolol Hydrochloride Injection, 100mg/10mL (10mg/mL), (ANDA 205520).

Esmolol Hydrochloride Injection, 100mg/10mL (10mg/mL) is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Brevibloc Injection, 10mg/mL of Baxter Healthcare Corporation.

Esmolol Hydrochloride Injection is indicated for the short-term treatment of tachycardia and hypertension that occur during induction and tracheal intubation, during surgery,on emergence from anesthesia and in the postoperative period.

Aurobindo now has 13 ANDAs (represented by 10 product classes) approved out of Unit IV formulation facility in Hyderabad for manufacturing general injectable products.