

Date: December 9, 2020

To  Listing Department, <b>NATIONAL STOCK EXCHANGE OF INDIA LIMITED</b> Exchange Plaza, Bandra Kurla Complex, Bandra (E), <b>MUMBAI -400 051</b>  <b>Company Code No. AUROPHARMA</b>	To  The Corporate Relations Department <b>BSE LIMITED</b> Phiroz Jeejeebhoy Towers, 25 <sup>th</sup> floor, Dalal Street, <b>MUMBAI -400 001</b>  <b>Company Code No. 524804</b>
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Dear Sirs,


**Sub: Press Release on USFDA approval for Dexmedetomidine HCL in 0.9% Sodium Chloride Injection**

We enclose a copy of the Press Release that is being issued by the Company in connection with USFDA approval received by the Company for Dexmedetomidine HCL in 0.9% Sodium Chloride Injection.

Please take the information on record.

Thanking you,

Yours faithfully,  
**For AUROBINDO PHARMA LIMITED**



B. Adi Reddy  
Company Secretary

Encl: As above

**AUROBINDO PHARMA LIMITED**

(CIN :L24239TG1986PLC015190)

PAN No. AABCA7366H

Corp off.: The Water Mark Building, Plot No.11, Survey No.9, Hi-tech City, Kondapur, Hyderabad – 500 084 T.S., INDIA Tel : +91 40 6672 5000 / 1200 Fax : +91 40 6707 4059  
Regd. Off. : Plot No. 2, Maitrivihar, Ameerpet, Hyderabad - 500 038 T.S., INDIA Tel : +91 40 2373 6370 Fax : +91 40 2374 7340, Email : info@aurobindo.com

[www.aurobindo.com](http://www.aurobindo.com)

NEWS RELEASE

09 Dec 2020, Hyderabad, India

**Aurobindo Pharma receives USFDA Approval for Dexmedetomidine HCL in 0.9% Sodium Chloride Injection**

Aurobindo Pharma Limited is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection, 200 µg/50 mL and 400 µg/100 mL Single Dose flexible containers (Bags). Aurobindo's Dexmedetomidine HCl in 0.9% Sodium Chloride Injection is a therapeutic equivalent generic version of Hospira's Precedex® in 0.9% Sodium Chloride Injection. The product will be launched in January 2021.

Dexmedetomidine Hydrochloride in 0.9% sodium chloride injection is a relatively selective alpha<sub>2</sub>-adrenergic agonist indicated for a) sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting; b) sedation of non-intubated patients prior to and/or during surgical and other procedures. The approved product has an estimated market size of US\$ 228 million for the twelve months ending October 2020 according to IQVIA.

This is the 79<sup>th</sup> ANDA to be approved out of Unit IV formulation facility in Hyderabad, India used for manufacturing injectable & ophthalmic products. Aurobindo now has a total of 459 ANDA approvals (431 Final approvals and 28 tentative approvals) from USFDA.

**About Aurobindo Pharma Limited:**

Aurobindo Pharma Limited ([www.aurobindo.com](http://www.aurobindo.com)) (NSE: AUROPHARMA, BSE: 524804, Reuters: ARBN.NS, Bloomberg: ARBP:IN), headquartered at Hyderabad, India, manufactures generic pharmaceuticals and active pharmaceutical ingredients. The company's manufacturing facilities are approved by several leading regulatory agencies like US FDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa, ANVISA Brazil. The company's robust product portfolio is spread over 7 major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, Anti-Allergies and Anti-Diabetics, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 150 countries.

**For further information, please contact:**

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**Disclaimer:**

This press release contain statements that may constitute "forward looking statements" including and without limitation, statements relating to product characteristics and uses, sales potential and target dates for product launch, implementation of strategic initiatives, and other statements relating to our future business developments and economic performance. While these forward looking statements represent our judgment and future expectations concerning the development of our business, a number of risks, uncertainties and other factors could cause actual developments and results to differ materially from our expectations. The Company undertakes no obligation to publicly revise any forward looking statements to reflect future events or circumstances and will not be held liable for any use of this information.

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