

February 7, 2025

To

Listing Department,

NATIONAL STOCK EXCHANGE OF INDIA LIMITED

Exchange Plaza, Bandra Kurla Complex, Bandra (E),

MUMBAI -400 051

**Company Code No. AUROPHARMA** 

To

The Corporate Relations Department

**BSE LIMITED** 

Phiroz Jeejeebhoy Towers, 25th floor, Dalal Street,

MUMBAI -400 001

Company Code No. 524804

Dear Sir / Madam,

Sub: Clarification w.r.t. intimation dated January 28, 2025 - US FDA

Ref: Our letter dated January 28, 2025 Your email dated February 6, 2025

With reference to the above, please find the details of action initiated by US FDA in the prescribed format as required under Regulation 30 of the SEBI Listing Regulations read with SEBI Master Circular No. SEBI/HO/CFD/PoD2/CIR/P/0155 dated November 11, 2024, are enclosed herewith as **Annexure.** 

Please take the information on record.

Yours faithfully,

For AUROBINDO PHARMA LIMITED

B. Adi Reddy Company Secretary

Enclosures: as above

**AUROBINDO PHARMA LIMITED** 

(CIN: L24239TG1986PLC015190)

www.aurobindo.com

Corp. Off.: Galaxy, Floors: 22-24, Plot No.1, Survey No.83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad – 500 032, Telangana, India. Tel: +91 40 6672 5000 / 6672 1200 Fax: +91 40 6707 4044.



## **Annexure**

S.No	Particulars	Details
1.	Name of the authority	U.S. Food and Drug Administration (US FDA), USA
2.	Nature and details of the action(s) taken, initiated or order(s) passed by the Authority	US FDA inspected an API manufacturing facility, Unit 2 of Apitoria Pharma Private Limited, a wholly owned subsidiary of the Company, situated at Gaddapotharam Village IDA, Jinnaram Mandal, Sanga Reddy District, Telangana, from September 23 to 27, 2024 and issued an Establishment Inspection Report (EIR) classifying the facility as Voluntary Action Indicated (VAI).
3.	Date of receipt of direction or order, including any ad-interim or interim orders, or any other communication from the authority	January 28, 2025
4.	Details of the violation(s)/ contravention(s) committed or alleged to be committed	US FDA during their inspection highlights the deviations from the cGMP standards and the same would be captured in Form 483. At the end of inspection, we received Form 483 with 10 observations which are of procedural nature and the same was intimated to exchanges on September 30, 2024.  The unit had on January 28, 2025 received an EIR classifying the facility as VAI and the same was intimated on January 28, 2025.
5.	Impact on financial, operation, or other activities of the listed entity, quantifiable in monetary terms to the extent possible	There is no impact on the Company's financials or operations due to the said action.

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