



**Biocon Limited**  
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CIN : L24234KA1978PLC003417

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

BIO/SECL/AJ/2023-24/104

October 18, 2023

To The Manager, <b>BSE Limited</b> Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To The Manager, <b>National Stock Exchange of India Limited</b> Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
<b>Scrip Code - 532523</b>	<b>Scrip Symbol - BIOCON</b>

**Subject: Company Statement**

Dear Sir/Madam,

Please find enclosed Company Statement w.r.t. **'Update on U.S. FDA Inspection at Biocon Biologics' Manufacturing Facility in Johor, Malaysia.'**

The above information will also be available on the website of the Company at [www.biocon.com](http://www.biocon.com).

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

*Mayank Verma*



**Mayank Verma**  
**Company Secretary and Compliance Officer**  
**Membership No.: ACS 18776**

Encl: Company Statement

## NOTIFICATION TO STOCK EXCHANGE

### COMPANY STATEMENT

## Update on U.S. FDA Inspection at Biocon Biologics' Manufacturing Facility in Johor, Malaysia

*Bengaluru, Karnataka, India, October 18, 2023*

“Biocon Sdn Bhd., a step-down subsidiary of Biocon Biologics Limited has received a communication from the U.S. Food and Drug Administration (FDA) pursuant to its July 2023 cGMP inspection at its insulins manufacturing facility at Johor, Malaysia. The FDA has determined the inspection classification as “OAI” (Official Action Indicated). The OAI status may cause delay and/or withholding of pending product approvals or supplements from the facility.

We submitted a comprehensive Corrective and Preventive Action (CAPA) plan to the FDA in response to observations from the July inspection and believe we are on track to complete all actions as committed. The Company will continue to engage with the Agency to understand any outstanding concerns and work closely to address them expeditiously.

We do not believe that this will have a material impact on the manufacturing and distribution of the Company's commercial products for the US market. Biocon Biologics remains committed to bringing high-quality and affordable medicines to patients in the United States.”

– Company Spokesperson

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For more information: [seema.ahuja@biocon.com](mailto:seema.ahuja@biocon.com)