



**Biocon Limited**  
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CIN : L24234KA1978PLC003417

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

BIO/SECL/AJ/2023-24/171

February 29, 2024

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 below a Company Statement.

*“The U.S. Food and Drug Administration (FDA) conducted an inspection at Biocon Biologics Limited’s Biocon Campus (Site 1) facility between February 20-28, 2024.*

*This inspection pertains exclusively to the rh-Insulin (rhl) Drug Substance (DS) supply to a customer for veterinary use. The trigger for this inspection was a Pre-Approval Supplement (PAS) filed by our customer late last year.*

*At the conclusion of this inspection, the agency has issued Form 483s with 4 observations. The Company will submit a comprehensive Corrective and Preventive Action (CAPA) Plan to the U.S. FDA within the stipulated time and is committed to addressing these observations expeditiously.*

*The outcome of this inspection at Site 1 does not impact the manufacturing and distribution of the Company’s commercial products in the US market.*

*Biocon Biologics remains committed to global standards of Quality and Compliance.” – Company Spokesperson*

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**

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