



Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

BIO/SECL/TG/2025-26/84

September 04, 2025

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

Subject: Company Statement

Dear Sir/Madam,

Please find enclosed Company Statement w.r.t. **“U.S. FDA Completes Inspection at Biocon Biologics’ Facility at Biocon Campus, Bengaluru, India”**.

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

Ekta Agarwal
Interim Company Secretary and Compliance Officer
Membership No.: FCS 11388

Encl: Company Statement

Notification to Stock Exchanges

COMPANY STATEMENT

U.S. FDA Completes Inspection at Biocon Biologics' Facility at Biocon Campus, Bengaluru, India

Bengaluru, Karnataka, India, September 4, 2025

The U.S. Food and Drug Administration (FDA) has completed a routine cGMP inspection at **Biocon Biologics'** Drug Substance facility at Biocon Campus in Bengaluru, India.

The inspection was held between August 26, 2025, and September 3, 2025, covering drug substance manufacturing units, analytical QC laboratories, microbiology laboratories, and warehouses.

At the conclusion of the inspection, the U.S. FDA issued a Form 483 with five observations. These observations are procedural in nature and do not pertain to data integrity, systemic non-compliance, or quality oversight.

Biocon Biologics will submit a comprehensive Corrective and Preventive Action (CAPA) plan within the stipulated timeline and is confident in its ability to address all observations expeditiously.

The company does not anticipate any impact on supply of its commercial products.

Biocon Biologics remains committed to upholding the highest standards of Quality and Compliance, and working collaboratively with global regulatory agencies to ensure the safety, efficacy, and reliability of its products.

– Company Spokesperson