



Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

BIO/SECL/TG/2026-27/11

April 30, 2026

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 – 400 051
Scrip Code - 532523	Scrip Symbol - BIOCON

Subject: Company Statement

Dear Sir/Madam,

Please find enclosed Company Statement w.r.t. **“U.S. FDA Completes Pre-License Inspection at Biocon’s Biosimilars Site at Biocon Park, 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**

Rajesh U. Shanoy
Company Secretary and Compliance Officer
M. No.: ACS 16328

Encl: Company Statement



Notification to Stock Exchanges

COMPANY STATEMENT

U.S. FDA Completes Pre-License Inspection at Biocon's Biosimilars Site at Biocon Park, Bengaluru, India

Bengaluru, Karnataka, India, April 30, 2026

The U.S. Food and Drug Administration (FDA) has completed a Pre-License Inspection (PLI) at Biocon's biosimilars site at Biocon Park in Bengaluru, India. The inspection was conducted between April 20, 2026, and April 29, 2026, and covered 3 Biologics Manufacturing units, 5 Quality testing laboratories and 2 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 or quality oversight. There were no repeat observations noted. The Company will submit a comprehensive Corrective and Preventive Action (CAPA) plan within the stipulated timeline and is confident all observations will be addressed fully and expeditiously.

Biocon 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