

**Biocon Biologics Limited**

CIN: U24119KA2016PLC093936  
Biocon House, Tower-3,  
Semicon Park Electronic City, Phase - II,  
Hosur Road, Bengaluru, Karnataka 560100 IN  
**T** +91 080-6775 6775, **F** +91 080-6775 1030  
**E** [contact@bioconbiologics.com](mailto:contact@bioconbiologics.com)  
[www.bioconbiologics.com](http://www.bioconbiologics.com)

April 30, 2026

**Singapore Exchange Securities Trading Limited**

4 Shenton Way # 02-01  
SGX Centre 2 Singapore 068807

Dear Sir/Madam,

**Subject: Company Statement**

Please find enclosed the company statement titled ***“U.S. FDA Completes Pre-License Inspection at Biocon’s Biosimilars Site at Biocon Park, Bengaluru, India”***.

Kindly take the same on record and acknowledge.

Thanking you

Your faithfully

**For Biocon Biologics Limited**

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Akhilesh Nand  
Company Secretary  
Membership No. ACS 13669

Encl: as above



## 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**