**Biocon Limited**
20th KM, Hosur Road
Electronic City
Bangalore 560 100, India
**T** 91 80 2808 2808
**F** 91 80 2852 3423

**CIN** : L24234KA1978PLC003417

**www.biocon.com**

BIO/SECL/SP/2024-25/102

September 28, 2024

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

Dear Sir/Madam,

**Subject: Notification to Stock Exchanges**

Please find enclosed the company statement titled **"US FDA Completes Inspection at Biocon Biologics' Insulins Facility at Johor Bahru, Malaysia".**

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**

MAYANK VERMA
Digitally signed by MAYANK VERMA
Date: 2024.09.28 17:10:26 +05'30'

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

Encl: as above

**NOTIFICATION TO STOCK EXCHANGE**

**Company Statement**

***Bengaluru, Karnataka, India, Sep 28, 2024***

# US FDA Completes Inspection at Biocon Biologics' Insulins Facility at Johor Bahru, Malaysia

"The U.S. Food and Drug Administration (FDA) conducted a cGMP inspection at Biocon Biologics' Insulins Manufacturing Facility in Malaysia between September 17, and September 27, 2024. The inspection scope included a number of biologics manufacturing units comprising one (1) Drug Substance and one (1) Drug Product manufacturing units, one (1) Medical Device Assembly unit, one (1) Analytical Quality Control Laboratory, two (2) Microbiological Control Laboratories and two (2) Warehouses.

The inspection concluded with the issuance of a form 483 with observations broadly categorized as: five (5) observations across the Drug Substance and Drug Product facilities; zero (0) observations on the Medical Device Assembly unit; three (3) observations on the Analytical & Microbiological Quality Control Laboratory; and zero (0) observations on the Warehouse operations.

There were no observations related to Data Integrity, Systemic Deficiencies or Quality Oversight at any of the units, noted by the agency, during the inspection.

Biocon Biologics will submit a comprehensive Corrective and Preventive Action (CAPA) plan to the agency and is confident of addressing these observations expeditiously. The Company does not foresee the outcome of these inspections to impact the supply of its commercial products. Biocon Biologics remains committed to global standards of Quality & Compliance and to serving patients across the world." *– Company Spokesperson*

*For more information: seema.ahuja@biocon.com*