



Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

BIO/SECL/AJ/2023-24/57

July 21, 2023

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 Two cGMP Inspections at Biocon Biologics' Insulins Facility in 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
Company Secretary and Compliance Officer
Membership No.: ACS 18776

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

U.S. FDA Completes Two cGMP Inspections at Biocon Biologics' Insulins Facility in Malaysia

Bengaluru, Karnataka, India, July 21, 2023

“The U.S. Food and Drug Administration (FDA) conducted two cGMP inspections at Biocon Sdn. Bhd’s Insulins Manufacturing Facility in Malaysia, encompassing Biologics Drug Substance, Drug Product units and Quality Control laboratories, as well as the Delivery Devices unit. These inspections were conducted between July 10 and July 20, 2023.

At the conclusion of these inspections, the agency issued a Form 483 with 6 observations for Drug Substance, Drug Product units and Quality Control laboratories as well as 2 observations for the Delivery Devices unit.

These observations primarily relate to enhancing operational procedures and strengthening training programs. The inspections did not identify any data integrity breaches or systemic non-compliance.

We will submit a Corrective and Preventive Action (CAPA) plan to the U.S. FDA in a timely manner and are confident of addressing these observations expeditiously.

Biocon Biologics remains committed to global standards of Quality and Compliance.”

– Company Spokesperson

For queries: seema.ahuja@biocon.com