



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

August 31, 2022

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 a Company Statement.

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**

Memel



Mayank Verma
Company Secretary and Compliance Officer

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Bengaluru, Karnataka, India, Aug 31, 2022

“The U.S. Food and Drug Administration (US-FDA) conducted **three on-site inspections of Biocon Biologics’ seven manufacturing facilities spanning two sites in Bengaluru, India and one at Johor, Malaysia.** These inspections started with the Bengaluru site on August 11, 2022 and concluded with the Malaysia site on August 30, 2022.

These inspections were triggered on account of three preapproval inspections for biosimilar Bevacizumab, rh-Insulin and Insulin Aspart and a capacity expansion inspection for biosimilar Trastuzumab. These included multiple drug substance and drug product facilities and other support infrastructure at these sites.

At the conclusion of these inspections, the agency has issued Form 483s with 11 observations each for the two sites in Bengaluru and 6 observations for the Malaysia site.

The observations primarily relate to the need for improving strategies for microbial control, enhancing quality oversight, augmenting the use of software applications & computerized tools to aid risk assessment & investigations and other procedural & facility upgrades.

We will submit Corrective and Preventive Action Plans (CAPA), to the US FDA in the stipulated time frame.

We do not expect the outcome of these inspections to impact the current supply of our products. Biocon Biologics remains committed to global standards of Quality and Compliance.

– Company Spokesperson