



Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

September 25, 2021

To The Manager, BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 Scrip Code - 532523	To The Manager, National Stock Exchange of India Limited Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 Scrip Symbol - Biocon
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Subject: Company Statement

Dear Sir/Madam,

Please find below a Company Statement titled **“Biocon Biologics Insulin Manufacturing Facility in Malaysia Completes U.S. FDA (PAI) Inspection.”**

“This is to inform you that the U.S. Food and Drug Administration (US-FDA) conducted an on-site pre-approval inspection (PAI) of our Malaysian subsidiary Biocon Sdn. Bhd’s manufacturing facility for Insulin Aspart between Sep 13 and Sep 24, 2021.

At the conclusion of the inspection, the agency has issued a Form 483 with a total of 6 observations across Drug Substance, Drug Product and Devices Facilities.

We are confident of addressing these observations through procedural enhancements and an appropriate Corrective and Preventive Action Plan (CAPA), which will be submitted to the US FDA in the stipulated time. We do not expect the outcome of this inspection to impact our commercialization plans for insulin Aspart in the US. Biocon Biologics remains committed to global standards of Quality and Compliance.” Company Spokesperson

For Further Information: seema.ahuja@biocon.com.

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