



Biocon Limited

20th KM Hosur Road

Electronics City

Bangalore 560 100, India

T 91 80 2808 2808

F 91 80 2852 3423

CIN : L24234KA1978PLC003417

February 22, 2020

www.biocon.com

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
--	--

Dear Sir/Madam,

Subject: Company Statement - Biocon's Insulin Manufacturing Facility in Malaysia Completes U.S. FDA (PAI) Inspection.

Please find below the "Company Statement" on the subject matter.

"This is to inform you that the U.S. Food and Drug Administration (FDA) conducted a pre-approval inspection (PAI) of our subsidiary, Biocon Sdn. Bhd's Insulins manufacturing facility based in Malaysia, for Insulin Glargine, between Feb 10 and Feb 21, 2020.

At the conclusion of the inspection, the agency issued a Form 483 with 3 observations which we believe are procedural in nature.

*We will respond to the FDA with an appropriate Corrective and Preventive Action Plan (CAPA) and are confident of addressing these observations expeditiously. The FDA has set a Target action date for our Insulin Glargine application in June 2020. We believe the outcome of this inspection does not in any way impact the commercialization plans of insulin glargine in the US. Biocon Biologics is committed to global standards of Quality and Compliance." - **Company Spokesperson***

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For Biocon Limited

Mayank



Mayank Verma
Company Secretary & Compliance Officer