Notification to Stock Exchange

Company Statement

Biocon Biologics Insulin Manufacturing Facility in Malaysia Completes U.S. FDA (PAI) Inspection

Bengaluru, Karnataka, India, Sep 25, 2021

"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

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