Notification to Stock Exchanges

COMPANY STATEMENT

U.S. FDA Completes Inspection at Biocon Biologics' Facility at Biocon Campus, Bengaluru, India

Bengaluru, Karnataka, India, September 4, 2025

The U.S. Food and Drug Administration (FDA) has completed a routine cGMP inspection at **Biocon Biologics'** Drug Substance facility at Biocon Campus in Bengaluru, India.

The inspection was held between August 26, 2025, and September 3, 2025, covering drug substance manufacturing units, analytical QC laboratories, microbiology laboratories, and warehouses.

At the conclusion of the inspection, the U.S. FDA issued a Form 483 with five observations. These observations are procedural in nature and do not pertain to data integrity, systemic non-compliance, or quality oversight.

Biocon Biologics will submit a comprehensive Corrective and Preventive Action (CAPA) plan within the stipulated timeline and is confident in its ability to address all observations expeditiously.

The company does not anticipate any impact on supply of its commercial products.

Biocon Biologics remains committed to upholding the highest standards of Quality and Compliance, and working collaboratively with global regulatory agencies to ensure the safety, efficacy, and reliability of its products.

– Company Spokesperson