

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

U.S. FDA Completes Two cGMP Inspections at Biocon Biologics' Insulins Facility in Malaysia

Bengaluru, Karnataka, India, July 21, 2023

“The U.S. Food and Drug Administration (FDA) conducted two cGMP inspections at Biocon Sdn. Bhd’s Insulins Manufacturing Facility in Malaysia, encompassing Biologics Drug Substance, Drug Product units and Quality Control laboratories, as well as the Delivery Devices unit. These inspections were conducted between July 10 and July 20, 2023.

At the conclusion of these inspections, the agency issued a Form 483 with 6 observations for Drug Substance, Drug Product units and Quality Control laboratories as well as 2 observations for the Delivery Devices unit.

These observations primarily relate to enhancing operational procedures and strengthening training programs. The inspections did not identify any data integrity breaches or systemic non-compliance.

We will submit a Corrective and Preventive Action (CAPA) plan to the U.S. FDA in a timely manner and are confident of addressing these observations expeditiously.

Biocon Biologics remains committed to global standards of Quality and Compliance.”

– Company Spokesperson

For queries: seema.ahuja@biocon.com