May 8, 2020

Dear Sir/Madam,

Subject: Biocon’s Receives EIR for Small Molecules API Manufacturing Facility for Pre-Approval and GMP U.S. FDA Inspection

Please find below the “Company Statement” on the subject matter.

“This is to inform you that Biocon has received the Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (FDA) for the Pre-Approval and GMP inspection of its Small Molecules API Manufacturing Facility at Biocon Park SEZ, Bommanasandra, Bengaluru, conducted between January 20 and January 24, 2020. At the conclusion of the inspection the agency had issued a Form 483, with five observations, which are being addressed by the Company. The EIR has been closed with a “VAI” classification for the observations.

We remain 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 Verma
Company Secretary and Compliance Officer