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Biocon’s Bengaluru unit completes inspection with zero observations

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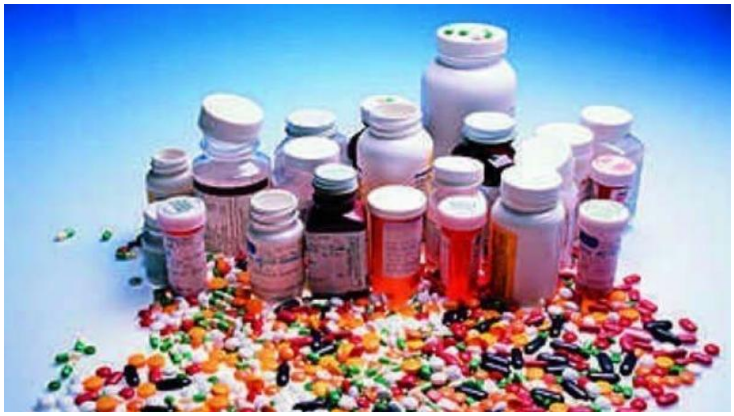
The company has announced that its oral solid dosage manufacturing facility completed pre-approval USFDA inspection with zero observations



Biocon is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It is a leading global player for high quality biosimilars, APIs including statins, immunosuppressants and specialty molecules.

The company has announced that its oral solid dosage manufacturing facility completed pre-approval USFDA inspection with zero observations.

The inspection of the Bengaluru facility, which took place between 13 and 17 January 2020, concluded with zero observations and no Form 483 was issued.

The company said in statement,"This is to inform you that the U.S. Food and Drug Administration (FDA) conducted a Pre-Approval Inspection (PAI) of the Oral Solid Dosage Manufacturing Facility of Biocon Pharma Ltd, a subsidiary of Biocon Ltd, which was triggered by the submission of an Abbreviated New Drug Application (ANDA).We remain committed to global standards of Quality and Compliance"