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Shares of Biocon continue to fall on US FDA observations

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The pharmaceutical watchdog from the US had inspected the companyâ??s Bengaluru plant, before issuing a Form-483 listing out the 8 observations



Shares of Biocon, India's largest and fully-integrated, innovation-led biopharmaceutical company, continue to fall for the third day today from May 10 after it received observations from US FDA in Form-483, leading to worries over further delay in approvals.

The pharmaceutical watchdog from the US had inspected the company's Bengaluru plant, before issuing a Form-483 listing out the 8 observations.

Reacting to the development, company in a statement to BSE noted "form 483 is a standard outcome of any audit. Biocon has already responded to US FDA on all observations of the recent audit within stipulated timelines.'

The spokesperson of the company in press statement said "As a policy we do not comment on any schedule or outcomes of regulatory inspections, unless we believe that there is a material impact. Biocon has a good track record of inspections by the US FDA, European regulators and other regulators from developed and emerging markets."

A Form- 483 is issued when the US FDA finds possible violations of the US Food Drug and Cosmetic Act after an investigation.

Biocon's share prices at BSE opened on May 12 at Rs 999 while it closed at Rs 1008 on May 10. The company's share prices touched a 52 week high of Rs 1188 and low of Rs 615.80.