

## Strides Shasun receives USFDA observations for Bengaluru unit

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**The company has been issued Form 483. As per the USFDA, Form 483 is issued to a firm management at the conclusion of an inspection when an investigator (s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.**



Strides Pharma Science has received three observations from the USFDA after the inspection of its formulations facility in Bengaluru.

“The formulations facility in Bangalore recently underwent pre-approval product inspection by the US Food and Drug Administration (USFDA). The inspection had ended on August 25, 2018 and the company has been issued Form 483 with 3 observations,” Strides Pharma Science has said in a regulatory filing.

The company believes that the observations are not material in nature and it has already responded to the USFDA. It has recently received a product approval for potassium chloride extended release tablets from the facility.

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