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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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