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Alkem Labs receives USFDA’s Form 483 with 2 observations

06 September 2019 | News

US FDA Inspection was carried out at Alkem's manufacturing facility located at Daman, India

Alkem Laboratories has announced that the US FDA had conducted an inspection at the Company's manufacturing facility located at Daman, India from 26th August, 2019 to 30th August, 2019.

At the end of the inspection, the Company has received a Form 483 with two (2) observations. The Company shall put together a detailed response with adequate corrective and preventive measures to address the US FDA observations and the same is proposed to be filed within the timeline stipulated by US FDA.