BioSpectrum the business of Bio & Health Sciences

Lupin's Mandideep plant comes under FDA scanner

30 March 2016 | News | By BioSpectrum Bureau

Lupin's Mandideep plant comes under FDA scanner

Lupin has received a total of three observations relating to violation of production norms at manufacturing facilities at its Mandideep plant in Madhya Pradesh from the US Food and Drug Administration(USFDA).

"We had an audit at our Mandideep location from February 2 to February 19. There were total of three observations. As the site has both dosage form facility and API facility, two separate form 483s were issued with two observations each. one of the observations was repeated in both the forms as it is relevant to both operations," Lupin said in a filing to BSE.

"These observations are minor in nature and we have already addressed these observations. We believe that the outcome of the audit will be voluntary action indicated only and there will be no remediation required," it added.

The company further said it does not expect any disruption to product supply from Mandideep location. There are no pending applications from the facility.