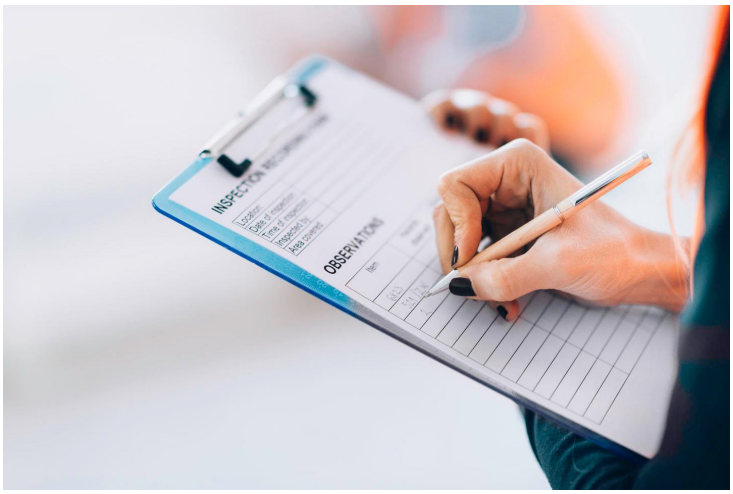
BioSpectrum
the business of Bio & Health Sciences

USFDA completes inspection of Lupin’s Mandideep location

06 December 2018 | News

The inspection at Unit-2, the Cardiovascular “Pril” API facilities closed with 4 observations



Lupin has announced the completion of United States Food and Drug Administration (US FDA) inspections carried out at its Mandideep location. Lupin’s Mandideep location houses the company’s cardiovascular “Pril” API facilities, Cephalosporin API facilities and Cephalosporin Solid Oral Dosage Form facility.

These inspections were carried out between November 26 and December 4, 2018.

The inspection at Unit-2, the Cardiovascular “Pril” API facilities closed with 4 observations.

The inspection at Unit-1, the Cephalosporin facilities closed with 10 observations for the Cephalosporin API facilities and 8 observations for the Cephalosporin Solid Oral Dosage Form facility.

The observations are largely procedural in nature with some gaps identified in the aseptic processing areas of the Cephalosporin API block and the company is confident of addressing them satisfactorily.