BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Cadila's Gujarat plant under USFDA scanner

01 August 2014 | News | By BioSpectrum Bureau

Cadila's Gujarat plant under USFDA scanner



Drug maker Cadila Healthcare has come under the US regulatory scanner with the US Food and Drug Administration (USFDA) expressing concern over the manufacturing process of at least one product at Cadila's Moraiya facility in Gujarat. The company will respond to the observations of the FDA, made after conducting a product specific inspection of its Moraiya manufacturing plant, a company spokeswoman said.

"This was a product specific review and the inspection was limited to the review of documents filed for ANDA before its approval and the observations are being responded to," a statement mentioned.

There is no business impact from the FDA action and Cadila has not received any observations on the standard manufacturing practices at the Moraiya plant, the spokesperson said.

The FDA communicated its concern to Cadila in a Form 483, the statement said. Once a Form 483 is issued by the FDA, the company has 15 days to respond before further action is taken.

Â

Cadila has one of the largest pipelines of 158 generic drugs awaiting approval from the FDA, according to the company filings.

Â

Â