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The United Stated Food and Drug Administration (US FDA) has issued warning letter (Form 483) to Natco Pharma and Orchid Chemicals and Pharmaceuticals, according to reports. The letter was issued after the regulatory body found deviations from the standard quality control practices. The US regulator inspected the two companies manufacturing plant earlier this year.

The US FDA inspected Natco pharma's dosage facility located in Mahabubnagar district in Telangana. In the letter, the regulatory body has said that the company does not have any written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess. It further mentioned that the company's quality control unit lacks responsibility to approve or reject procedures that impact quality and purity of drugs.

Similarly, the regulatory body has raised concerns over the Orchid Chemicals and Pharmaceuticals's quality system after inspecting its manufacturing unit located in Waluj, Maharashtra in April 2014. It said that the company's test procedures are not scientifically sound and appropriate to ensure that raw materials, intermediates and active pharmaceutical ingredients (APIs) conform to established standards of quality and purity. Also, equipment cleaning/sanitation study does not address microbiological and endotoxin contamination for those processes where there is a need to reduce total microbiological count or endotoxins in the API, or other processes where such contamination could be of concern.