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United States Federal Drug Approval (USFDA) has issued a letter to the COO of Apotex Mr Jeremy B Desai. Th letter was issued after investigators identified significant deviations from current good manufacturing practice (CGMP) for the manufacture of active pharmaceutical ingredients (APIs) in the company's Bangalore plant.

In the report, the regulatory has said that the company failed to maintain complete data, derived from laboratory tests conducted. The tests need to comply with established specifications and standards. It asked the company to provide a list of all the batches of APIs in distribution and those intended to be shipped to the US market that relied upon "the missing, inaccurate, or unreliable test data".

The FDA said that it may withhold approval of any new applications or supplements listing it as an API manufacturer until the regulatiory body has confirmed that all corrections of the deviations have been carried out. It further warned that failure to correct these deviations may result in FDA continuing to refuse admission of drugs manufactured at Apotex Pharmachem India.

The company has 15 working days to notify FDA of the specific steps that the company has taken to correct and prevent the recurrence of deviations, and provide copies of supporting documentation.