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# USFDA grants NAI to Centaur Pharma's FD facility in Pune

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**The company received No Action Indicated (NAI) compliance status with zero 483 observations from the USFDA**

Mumbai based Centaur Pharmaceuticals' finished dosage facility in Pune was audited by the USFDA in May 2019 and the audit was concluded with NIL 483 observations. The company received No Action Indicated (NAI) compliance status with zero 483 observations from the USFDA which signifies compliance and conformance to applicable cGMP regulations

According to Mr. S.D Sawant, Managing Director, Centaur Pharmaceuticals "The NAI is a significant development not only for Centaur but also for the Indian pharmaceutical industry, considering the increasing global regulatory headwinds in the last few years." In addition to USFDA accreditation, the said facility also conforms to MHRA (UK), TGA (Australia), Health Canada, MCC (South Africa) and WHO-GMP standards.

If the investigating officer observes conditions which in his or her judgment are violations of the Food Drug and Cosmetic (FD&C) Act or related acts, then he or she may issue the concerned firm an FDA Form 483. On the other hand, an inspection results in a NAI inspection classification when the inspection either reveals no objectionable conditions or that the significance of the documented objections does not warrant further action. This classification signifies the compliance status of the concerned establishment at the time of inspection, based on the recorded observations.

"The conclusions of the inspection are reported as No Action Indicated (NAI) which is vindication of Centaur's efforts over the past 40 years in ensuring quality and maintaining international standards across the pharmaceutical value chain in API, formulations, clinical research and contract manufacturing" says Dr. Jayashing Sawant, President- Technical, Centaur Pharmaceuticals.

Centaur is also India's largest and the world's third largest manufacturer of psychotropic API with state of the art facility conforming to USFDA, EUGMP/ANSM (France), TGA, PMDA (Japan), KFDA (Korea), ANVISA (Brazil), COFEPRIS (Mexico) and WHO-GMP standards. Centaur's API (Active Pharmaceuticals Ingredients) formulations plant situated in Ambernath, Maharashtra is also an US FDA approved plant. In addition, Centaur Pharmaceuticals also has two world class formulations facilities in Goa which are WHO-GMP approved.