

MEDIA RELEASE



Torrent Pharmaceuticals gets EIR from US FDA for Dahej facility

Ahmedabad, August 24, 2023: Torrent Pharmaceuticals Limited ("Torrent") has announced that the US drug regulator US Food and Drug Administration (US FDA) has issued an Establishment Inspection Report ("EIR") for the company's manufacturing facility at Dahej, Gujarat, and that the inspection has now been successfully closed by the US FDA.

Based on the March 2019 Inspection outcome, the Dahej facility was placed under "Official Action Indicated (OAI)" by the US FDA. The drug regulator had conducted re-inspection of the site in May 2023 from 17-May-23 to 25-May-23 and issued Form 483 with 2 observations.

The updated classification of site is VAI (voluntary action indicated) which indicates that Torrent will start to get approval of filed ANDAs. This will further enhance the company's prospects and foster growth in the US market with its new product offerings.

The Dahej facility manufactures APIs and formulations for Torrent Pharma's international markets.

About Torrent Pharmaceuticals Ltd:

Torrent Pharma, with annual revenue of more than Rs 9,600 crores, is the flagship Company of the Torrent Group, with group revenue of ~Rs. 37,000 crores. It is ranked 6th in the Indian Pharmaceuticals Market and is amongst the Top 5 in the therapeutics segments of Cardiovascular (CV), Gastro Intestinal (GI), Central Nervous System (CNS), Vitamins Minerals Nutritional (VMN) and Cosmo-Dermatology. It is a specialty-focused company with ~75% of its revenue in India from chronic & sub-chronic therapies. It has presence in 50+ countries and is ranked No. 1 amongst the Indian pharma Companies in Brazil, Germany and Philippines. Torrent has 8 manufacturing facilities, of which 5 are USFDA approved. With R&D as the backbone for its growth in domestic & overseas market, it has invested significantly in R&D capabilities with state-of-the-art R&D infrastructure employing approximately 750 + scientists.

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