ALKEM

ALKEM LABORATORIES LTD.

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Alkem receives EIR from the US FDA for its Alkem's Ankaleshwar API Facility

Mumbai, 29th March, 2017: Alkem Labs Ltd (Alkem) would like to inform that the US FDA has issued an Establishment Inspection Report (EIR) for its Ankaleshwar API Facility which was inspected in December 2016. The inspection has now been closed by the US FDA.

The US FDA had inspected the Ankaleshwar API manufacturing facility from 5th to 9th December, 2016 and had issued Form 483 with three (3) observations. Post this, the Company had submitted a detailed corrective and preventive action (CAPA) plan to the regulator within the stipulated timelines. The US FDA has reviewed the CAPA and has found them acceptable.

About Alkem Laboratories Ltd.

Established in 1973 and headquartered in Mumbai, Alkem (NSE: ALKEM, BSE: 539523, Bloomberg: ALKEM.IN, Reuters: ALKE.NS) is a leading Indian pharmaceutical company with global operations, engaged in the development, manufacture and sale of pharmaceutical and nutraceutical products. The Company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals, which it markets in India and International markets. With a portfolio of more than 700 brands in India, Alkem is ranked the fifth largest pharmaceutical company in India in terms of domestic sales (Source: IMS SSA MAT March 2016). The Company also has presence in more than 50 international markets, with the United Stated being its key focus market.

For more information on Alkem Laboratories Ltd., please visit www.alkemlabs.com

For further information or queries please contact

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