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Alembic Pharma, Vadodara announces completion of USFDA inspection

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US Food & Drug Administration (USFDA) through its recent inspection of Alembic Pharma Vadodara facility concluded that there were no 483s issued at the end of the inspection

Alembic Pharmaceuticals Limited is one of the leading pharmaceutical companies in India. The company aims to explore opportunities in the therapeutic areas such as Dermatology, Oncology, and Injectable Formulations. APL also has also co-promoted a company focused on discovery and development of innovative, small molecule drugs that target signal transduction networks and ion channels for the treatment of cancer, inflammation, autoimmune diseases and metabolic disorders.

The company has established a state-of-the-art research facility – Alembic Research Centre (ARC)-including formulation research, and 150-bed bioequivalence facility at Vadodara, Gujarat. Additionally, APL has recently invested in ultra-modern R&D center at Hyderabad. APL is one of the leading players in the industry to have invested about 11% of its turnover in R&D.

USFDA inspected Alembic Pharmaceuticals Ltd bioequivalence facility at Vadodara between August 12, 2019 and August16, 2019 and also between August 12, 2019 and August 20, 2019 for bioequivalence bioanalytical and bioequivalence clinical compliance.

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An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any condition that in their judgment may constitute violation of the Food Drug and Cosmetic (FD&C) Act and related Acts.