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Strides Arcolab facility gets USFDA approval

Our Bureau

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Strides Arcolab, manufactures of niche pharmaceutical products, has got the United States Federal and Drug Administration's (USFDA) zero inspectional observation for its oral dosage forms manufacturing site in Bangalore.

The facility titled 'KRS Gardens' in Bangalore was recently inspected by the US FDA as part of GMP compliance audit and the facility continues to be approved with 'Zero Inspectional observation' reported in FDA 483.

"The US FDA's Zero observation in FDA 483 has no business implication but continues the growth of Strides' in the regulated markets of United States and Europe," said Mr Manish Gupta, Chief Executive Officer – Pharma of Strides.

"The development also augurs very well for the pharmaceutical division of the company in the challenging regulatory and business environment in the regulated markets," he added.

The last US FDA inspection and approval for this facility was in the year 2008. The Bangalore facility manufactures oral dosage forms such as tablets and capsules (both hard gelatine and soft gelatine). The manufacturing plant supports important current and future submissions to the US market.

The company has 14 manufacturing facilities across six countries with presence in more than 75 countries in developed and emerging markets. Manufacturing is supported by a 350-scientist strong global research and development (R&D) centre in Bangalore.