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Strides receives USFDA EIR for Bengaluru manufacturing facility

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The USFDA has concluded its inspection of Strides Pharma Scienceâ??s flagship Bengaluru site with a Voluntary Action Indicated classification following corrective and preventive actions.

Strides Pharma Science has received an Establishment Inspection Report from the United States Food and Drug Administration for its flagship manufacturing facility in Bengaluru, India, formally concluding the agency's recent inspection of the site.

The USFDA conducted a current Good Manufacturing Practices inspection at the facility from 12 to 20 May 2026.

The inspection concluded with the issuance of a Form 483 containing five observations. Strides subsequently submitted a response addressing the observations within the stipulated timeline.

Following review of the company's response and the corrective and preventive actions implemented, the USFDA classified the inspection outcome as Voluntary Action Indicated and issued the Establishment Inspection Report.

The EIR formally closes the inspection process.

The Bengaluru facility is Strides' flagship manufacturing site and serves regulated and other international markets.

The site manufactures a broad range of pharmaceutical dosage forms, including tablets, capsules and oral liquids, supporting both existing commercial products and future growth opportunities.

Strides said the inspection closure strengthens its regulatory track record and supports its continued supply of pharmaceutical products to global markets.

The company operates manufacturing facilities in India, Italy, Kenya and the United States and focuses on regulated markets as well as donor-funded and institutional businesses.

Strides' portfolio includes products that it describes as difficult to manufacture and are sold in more than 100 countries.