

USFDA announces Laboratory testing and analysis of Ranitidine and issues statement with acceptable NDMA limits

Strides' Ranitidine Tablets 300 mg lots tested by USFDA are within the acceptable NDMA limits

November 04, 2019: The USFDA issued a statement¹ on November 1, 2019 providing an update with the latest information on Ranitidine. The agency tested numerous ranitidine products on the market over the past few months and released a summary of the results they have to date. In this statement, USFDA indicated if they or the manufacturers find NDMA levels above the acceptable limits (96 nanograms per day or 0.32 ppm), they are now asking companies to recall ranitidine voluntarily. **In the summary of test results² provided by USFDA, Strides' Ranitidine Tablets 300 mg (Rx) is within the acceptable limits for NDMA of 96 nanograms per day or 0.32 ppm.** Several batches of other manufacturers are above this limit requiring a voluntary recall.

The Company intends to provide additional updates in the next coming days, including **potential recommencement** of product distribution by Strides of Ranitidine Rx based on available test results.

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bangalore, India. The Company mainly operates in the regulated markets and has an "in Africa for Africa" strategy along with an institutional business to service donor-funded markets. The Company's global manufacturing sites are located in India- Bangalore (two locations), Pondicherry, and Chennai, Singapore, Italy- Milan, Kenya- Nairobi and United States-Florida. The Company focusses on "difficult to manufacture" products that are sold in over 100 countries. Additional information is available at the Company's website at www.strides.com

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¹ https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs

https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine