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Strides to relaunch Ranitidine tablets for the US Market

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Product to be relaunched with immediate effect

Strides Pharma Science Limited (Strides or company) has announced relaunch of Ranitidine tablets for the US market. USFDA had tested numerous ranitidine tablets on the market over the past few months and released a summary of the results on November 1, 2019.

The agency had indicated that if the NDMA levels were above the acceptable limits (96 nanograms per day or 0.32 ppm), they are asking companies to recall ranitidine products voluntarily. Strides' Ranitidine Tablets 300 mg (Rx) were within the acceptable limits for NDMA of 96 nanograms per day or 0.32 ppm. Strides has now completed comprehensive testing of several of its batches available in market and in stock meeting the limits prescribed by the USFDA. Basis the outcome company has decided to relaunch its product with immediate effect.

Strides have approvals for Ranitidine tablets USP 150 mg and 300 mg. According to IQVIA MAT data, the US market for Ranitidine tablets USP 150 mg and 300 mg is ~ US$ 76 Mn. The company also has approvals for several OTC strengths but has not commercialized these products.