

USFDA approves Strides Loratadine OTC Softgel Capsules

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Product to be manufactured at the flagship facility in Bangalore



Strides

Strides Pharma Science Limited (Strides) announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for Loratadine Softgel Capsules, 10 mg (OTC) from the United States Food & Drug Administration (USFDA). The product is a generic version of Claritin® LiquiGels® Capsules, 10 mg, of Bayer HealthCare LLC.

Strides is focusing on building a private label business in the US by leveraging its portfolio of products across soft gels, tablets, capsules and other proprietary formats. Loratadine Softgel Capsules, 10 mg (OTC) is part of Strides niche and small volume product portfolio with limited competition in the US private label market. According to IRi data, the US market for Loratadine Softgel Capsules, 10 mg (OTC) is approximately US\$ 50 Mn with only one other generic approval. The product will be manufactured at the company's Oral dosage facility at Bangalore.

The company has 102 cumulative ANDA filings with USFDA of which 68 ANDAs have been approved and 34 are pending approval.