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Dr Reddy's recalls 9,330 bottles of Sirolimus tablets in the US

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According to the latest Enforcement Report of United States Food and Drug Administration (USFDA), Dr Reddy's US arm Dr Reddy's Laboratories Inc is recalling 9,330 bottles of Sirolimus tablets, 1 mg on account of failed impurities.

As per the report, the reason for recall is "failed impurities/degradation: out of specification result for impurity secorapamycin." The voluntary nationwide ongoing recall is a class III recall.

As per USFDA a class III recall is initiated in a "situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences."

The tablets were manufactured by Dr Reddy's Laboratories at its Visakhapatnam plant. Sirolimus tablets are indicated for the prevention of organ rejection in patients aged 13 years or older receiving renal transplants.

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