

Aurobindo gets USFDA nod for Guaifenesin Extended-Release Tablets

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Aurobindo Pharma Limited, headquartered at Hyderabad, India, manufactures generic pharmaceuticals and active pharmaceutical ingredients. Aurobindo Pharma is pleased to announce that the company has received final approval from the US Food & Drug Administration (USFDA) to manufacture Guaifenesin extended-release tablets, 600 mg and 1200 mg (OTC).

Aurobindo's Guaifenesin extended-release tablets are the AB rated generic equivalent of RB Health (US) LLC's Mucinex® tablets. The product is expected to launch in Q4FY20. Guaifenesin extended-release tablets help to loosen phlegm (mucus), and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

The approved product has an estimated market size of US\$ 301 million for the twelve months ending July 2019, according to IRI database. This is the 10th ANDA (including 1 tentative approval) approved out of Unit X formulation facility in Naidupet, Andhra Pradesh, India used for manufacturing oral products. Aurobindo now has a total of 419 ANDA approvals (392 Final approvals including 21 from Aurolife Pharma LLC and 27 tentative approvals) from USFDA.