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Alembic Pharma gets USFDA nod for Xylocaine pain relief ointment

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The approved product is therapeutically equivalent to AstraZeneca Pharmaceuticals' Xylocaine ointment, 5 per cent

Alembic Pharmaceuticals Limited has announced that its joint venture Aleor Dermaceuticals Limited has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Lidocaine Ointment USP, 5%.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Xylocaine Ointment, 5%, of AstraZeneca Pharmaceuticals LP (AstraZeneca).

Lidocaine Ointment USP, 5% are indicated for production of anesthesia of accessible mucous membranes of the oropharynx. It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin and insect bites.

Lidocaine Ointment USP, 5%, has an estimated market size of $ 97 million for twelve months ending December 2017 according to IQVIA. Alembic has a cumulative total of 79 ANDA approvals (66 final approvals and 13 tentative approvals) from US FDA, including this first ANDA approval for Aleor.