Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2015-CE-03738-1

Issued to:

Alkem Laboratories Limited

Manufacturing Site Address:

Plot No. 289-290 G.I.D.C.
Ankleshwar Bharuch, Gujarat 393002
INDIA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of Active Pharmaceutical Ingredients (APIs) has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing API manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 18 April 2016 to 21 April 2016, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 15 January 2009.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 21 October 2019

ISSUE DATE: 24 June 2016

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Stephen Hart, Senior Inspector
Manufacturing Quality Branch

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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TGA Health Safety Regulation