APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country **Australia**

This public document

2. has been signed by **Krystle Marquet**
3. acting in the capacity of **Departmental Officer**
4. bears the seal/stamp of **Department of Health**

Certified

5. at **Sydney Passport Office**
6. **the 31st day of July, 2017**
7. by **Terrianne Galvin**
8. No. **UPPT-N6-53167**
9. Seal/Stamp
10. Signature

State Office,
Sydney Passport Office

DEPARTMENT OF FOREIGN AFFAIRS AND TRADE * SYDNEY *

This Apostille only certifies the authenticity of the signature (where applicable) and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued. This Apostille can be verified at https://orao.dfat.gov.au/pages/verifyapostille.aspx

Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-CE-04045-1

Issued to:

Apotex Research Private Limited

Manufacturing Site Address:

Plot No 1 & 2 Bommasandra Industrial Area, 4th Phase Jigani Link Road
Bangalore 560 099 India

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer 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 manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on the 6th, 7th, 10th and 11th April 2017, 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: 11 April 2020

ISSUE DATE: 21 June 2017

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

Signed: .....

David Rowbury, 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.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-CE-04045-1

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Capsule, hard	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Registered Therapeutic Good	Finished Product Manufacture

The following limitations are applicable to these manufacturing operations:

The manufacturer is not certified to manufacture products containing any steroids, hormones, cytotoxic or cytostatic and antineoplastic components.

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

Signed: .....

David Rowbury, Senior Inspector
Manufacturing Quality Branch

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