

ORIGINAL
CERTIFICATE NO.
MCGM1600519

## Health Sciences Authority Republic of Singapore

THE MEDICINES ACT (CHAPTER 176)

#### GOOD MANUFACTURING PRACTICE CERTIFICATE

A certificate is hereby granted under the Medicines Act to

Pfizer Asia Pacific Pte Ltd

With manufacturing premises at 31 TUAS SOUTH AVENUE 6 SINGAPORE 637578

With store at

31 TUAS SOUTH AVENUE 6 SINGAPORE 637578

From the knowledge gained during the audit/conformity assessment performed by the Health Sciences Authority, Singapore from 27 September 2016 to 29 September 2016, it is considered that the manufacturer has maintained an overall acceptable level of compliance with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products (Part II) relating to active pharmaceutical ingredients, which encompasses all the recommendations of the World Health Organization (WHO) in relation to GMP.

Pharmaceutical dosage form(s), active pharmaceutical ingredient(s) or product(s) in respect of which the manufacturer is certified:

See attached.

Manufacturing Process Detail(s):

See attached.

This certificate shall not be reproduced except in full. It remains the property of the Health Sciences Authority and must be returned upon written demand. The authenticity and validity of this certificate may be verified by contacting the certifying Authority stated on this certificate.

This certificate takes effect from 27 September 2016, and unless revoked shall expire on 26 September 2019.

Date of Issue

13 February 2017

Fee

\$6000

Application No

1693264F

AUDIT AND LICENSING DIVISION

Health Products Regulation Group Health Sciences Authority

11 Biopolis Way

#11-01 Helios, Singapore 138667

Email: HSA\_Certification@hsa.gov.sg

OF FOREIGN PARTY

17030664

Dr CHOONG May Ling, Mimi for Licensing Authority

Certified true signature/ true document/true copy

BD018 0 MAD 2017

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### CONSULADO DE CHILE EN SINGAPUR

El Cónsul de Chile que suscribe certifica la autenticidad de la firma de don Chile Tul

LINGUI MONISTONIO

Actuación Nº 6910 Arancel Art. Nº 10

US\$ 12

Singapur 69 de Mouvo de 2007



Sergio Narea Consul de Chile

DE RELACIONES EXTERIORES DE CHILE

2 4 MAR 2017

Washington PIZARRO RIVEROS Oficial de Legalizaciones



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PHARMACEUTICAL DOSAGE FORM(S), ACTIVE PHARMACEUTICAL INGREDIENT(S) OR PRODUCT(S) IN RESPECT OF WHICH THE MANUFACTURER IS CERTIFIED:

#### To manufacture the following:

Active Pharmaceutical Ingredient (API)

- 1. Pregabalin
- 2. Linezolid
- 3. Desvenlafaxine Succinate
- 4. Celecoxib
- 5. Sunitinib Malate
- 6. Other APIs except Penicillins, Cephalosporins, Hormones, Cytotoxic Substances, Biological Substances, Steriods and Sterile Substances.

To conduct primary assembly of the following:

Nil

To conduct secondary assembly of the following:

Nil

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#### MANUFACTURING PROCESS DETAIL(S):

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- This certification applies to the manufacture, including the receipt of materials, production, packaging, labelling, quality control, release, storage and distribution of the above-mentioned active pharmaceutical ingredient(s) for use in human drug (medicinal) products.
- 2. This certification is a statement of the manufacturing quality system standard of the factory and is not an endorsement of the quality of the product(s) manufactured.

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