



Health Sciences Authority
Republic of Singapore
THE MEDICINES ACT (CHAPTER 176)

ORIGINAL
CERTIFICATE NO.
MCGM1600519

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

17030664

Mk Choong
Dr CHOONG May Ling, Mimi
for Licensing Authority

Certified true signature/
true document/true copy



CONSULADO DE CHILE EN
SINGAPUR

El Cónsul de Chile que suscribe certifica la autenti-
cidad de la firma de don Chel En

Thiam, Ministerio
PP-EE Singapur

Actuación N° 64/19 Arancel Art. N° 08/10

US\$ 12/-

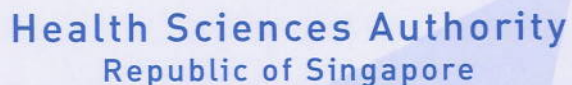
Singapur 09 de Marzo de 2017



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Sergio Narea
Consul de Chile





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

6. Other APIs except Penicillins, Cephalosporins, Hormones, Cytotoxic Substances, Biological Substances, Steroids and Sterile Substances.

Nil





MANUFACTURING PROCESS DETAIL(S):

1. 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.

