**ORIGINAL**
CERTIFICATE NO.
**MCGM2000381**

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

Glaxo Wellcome Manufacturing Pte Ltd

With manufacturing premises at

1 PIONEER SECTOR 1 SINGAPORE 628413

With store at

1 PIONEER SECTOR 1 SINGAPORE 628413

From the knowledge gained during the audit/conformity assessment performed by the Health Sciences Authority, Singapore on 24 to 28 August 2020 and 31 August to 1 September 2020, 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 24 August 2020, and unless revoked shall expire on 23 August 2023.

| | | |
|---|---|---|
| Date of Issue | : | 19 October 2020 |
| Fee | : | $6180 |
| Application No | : | 2075675K |

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

Dr CHOONG May Ling, Mimi
for Licensing Authority

Health Sciences Authority
Republic of Singapore

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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. Active Pharmaceutical Ingredients except Penicillins, Cephalosporins, Hormones, Cytotoxic Substances, Biological Substances 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):

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.