

PRG (AI)



HSA
Health Sciences Authority

Health Products Regulation Group

Health Sciences Authority
150 Cantonment Road
Cantonment Centre, Blk A, #01-02
Singapore 089762
Tel: 65 68663510 Fax: 65 64789068
Website: www.hsa.gov.sg

To whom it may concern

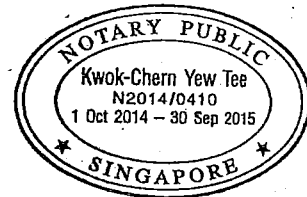
LIST OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) MANUFACTURED

This letter serves to clarify that the list of commercial APIs as described in this letter and declared to be manufactured by [redacted] located at [redacted], is consonant to the scope of the APIs attested in the Good Manufacturing Practice (GMP) Certificate (MCGM1200737) issued to the said company. ✓

2 List of APIs declared:

*P
DR* *1/2*

CERTIFIED TRUE COPY



3 This advice is given without prejudice to any future legislative amendments, new legislations or regulatory policies that may be gazetted or implemented from time to time.



Please
require any

Yours sincerely

LICENSING & CERTIFICATION BRANCH
AUDIT & LICENSING DIVISION
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY
SINGAPORE





ORIGINAL
CERTIFICATE NO.

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

CERTIFICATE NO. COPY

With manufacturing premises at

With store at



From the knowledge gained during the audit/conformity assessment performed by the Health Sciences Authority, Singapore from 2, 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 21 and unless revoked shall expire

Date of Issue :

Fee

Application No

A
J
J

9762

Dr. John Lim
for Licensing Authority



ORIGINAL
CERTIFICATE NO

Health Sciences Authority
Republic of Singapore

**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)

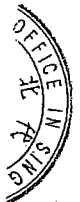
1. Active Pharmaceutical Ingredients except Penicillins, Cephalosporins, Hormones, Cytotoxic Substances,
Biological Substances and Sterile Substances.

To conduct primary assembly of the following:

Nil

To conduct secondary assembly of the following:

Nil





ORIGINAL
CERTIFICATE NO.

Health Sciences Authority
Republic of Singapore

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.