



NC0P260KOF

NOTARIAL CERTIFICATE

TO ALL TO WHOM these presents shall come

I, Ho Suk Tsing Leslie, NOTARY PUBLIC duly admitted, authorised to practise in the Republic of Singapore, DO HEREBY CERTIFY

THAT I have compared the document "HEALTH SCIENCES AUTHORITY - REPUBLIC OF SINGAPORE - GOOD MANUFACTURING PRACTICE CERTIFICATE - CERTIFICATE NO. GMPAP2400010P - DATE OF ISSUE: 22 July 2024" relating to AVENTIS PHARMA MANUFACTURING PTE LTD hereunto annexed with the original AND DO certify the said document to be a true copy of the original document.

IN FAITH AND TESTIMONY whereof I the said notary have subscribed my name and set and affixed my seal of office at Singapore, this 20th day of March 2025.



NOTARY PUBLIC
SINGAPORE



By virtue of Rule 8(3)(c) of the Notaries Public Rules, a Notarial Certificate must be authenticated by the Singapore Academy of Law in order to be valid.

With effect from 16 September 2021, a Notarial Certificate shall be deemed to be validly authenticated by the affixing of an Apostille to the back of the Notarial Certificate.



APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

This **Apostille** only certifies the authenticity of the signature, seal or stamp and the capacity of the person who has signed the attached Singapore public document, and, where appropriate, the identity of the seal or stamp. It does not certify the authenticity of the underlying document.

If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country.

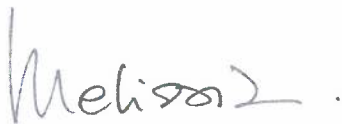
To verify this **Apostille**, go to

<https://legalisation.sal.sg>

or scan QR code:



Verification code: 58117452

1. Country:	Singapore
This public document	
2. Has been signed by:	Ho Suk Tsing Leslie
3. Acting in the capacity of:	Notary Public
4. Bears the seal/stamp of:	Notary Public
Certified	
5. At:	Singapore Academy of Law
6. The:	20th March 2025
7. By:	Melissa Goh, Director, Trust Services, SAL
8. No.:	AC0P270FWB
9. Seal/Stamp:	10. Signature: 





Health Sciences Authority
Republic of Singapore

ORIGINAL
CERTIFICATE NO.
GMPAP2400010P

HEALTH PRODUCTS ACT 2007

GOOD MANUFACTURING PRACTICE CERTIFICATE

A certificate is hereby granted under the Health Products Act 2007 to
AVENTIS PHARMA MANUFACTURING PTE LTD

With manufacturing premises at
61 GUL CIRCLE SINGAPORE 629585

With store at: See attached.

From the knowledge gained during the audit/conformity assessment performed by the Health Sciences Authority, Singapore on 09-10 May 2024 and 13-14 May 2024, 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.

Active Ingredient(s) in respect of which the manufacturer is certified: See attached.

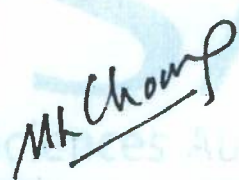
Any restrictions or clarifying remarks related to the scope of this certificate: See attached.

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 09 May 2024, and unless revoked shall expire on 08 May 2027.

Date of Issue : 22 July 2024
Application : 2486659X

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

CERTIFIED TRUE COPY





Health Sciences Authority
Republic of Singapore

ORIGINAL
CERTIFICATE NO.
GMPAP2400010P

WITH STORE AT:

61 GUL CIRCLE SINGAPORE 629585

HSA
Health Sciences Authority



Health Sciences Authority
Republic of Singapore

ORIGINAL
CERTIFICATE NO.
GMPAP2400010P

ACTIVE INGREDIENTS IN RESPECT OF WHICH THE MANUFACTURER IS CERTIFIED:

Manufacture

Active Ingredients

1. Non-Sterile Chemical Active Ingredients

Manufacturing Processes

1. Non-Sterile Active Ingredients
 - 1.1. Chemical Synthesis
 - 1.1.1. Crystallisation
 - 1.1.2. Salt Formation, Purification
 - 1.2. Physical Processing Steps
 - 1.2.1. Milling
 - 1.2.2. Micronisation
 - 1.2.3. Granulation

Quality Control Testing

1. Chemical/Physical
2. Microbiological
3. Biological

To conduct primary packaging of the following:

1. Chemical Active Ingredients

To conduct secondary packaging of the following:

1. Chemical Active Ingredients



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List of Active Ingredients

1. Enoxaparin sodium
2. Sodium cromoglicate



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Any restrictions or clarifying remarks related to the scope of this certificate

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 active ingredients manufactured.