Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Alice Yang
Vitopharm Biotech Pty Ltd
SE 603/100 Walker St
North Sydney NSW 2060

Dear Alice

Subject: Application(s) for Certificate(s) of a Pharmaceutical Product/ Certificate(s) of Listed Product

I refer to your application(s) requesting Certification of a Pharmaceutical Product (CPP) or Certification of Listed Product (CLP).

Please find enclosed the certification requested.

Yours Sincerely,

Export Officer
Application entry, support and export
Prescription Medicines Authorisation Branch
tga.exports@health.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of a Listed Product[1]

37294

Exporting (certifying) country: **Australia**
Importing (requesting) country: **Vietnam**

1. **Name and dosage form of product:**
5-MTHF Biologically Active Folate

Certificate No. 24/1592

1.1 **Active ingredient(s)[2] and amount(s) per unit dose[3] (if applicable) :**
(for complete composition including excipients see Schedule 1, attached to this Certificate)

1.2 **Is this product licensed to be placed on the market for use in the exporting country?[4]** YES

TGA comment:	**This product has been approved by the TGA and is permitted for free sale (in that it can be legally supplied) in Australia[8]**

Sponsor comment:	**Product Category in Vietnam: Health Supplement**

2.

Listing No: AUST L 445966	19 April 2024
Name and address of applicant:	Vitopharm Biotech Pty Ltd SE 603/100 Walker St North Sydney NSW 2060 AUSTRALIA
Status of applicant[5]: (c)	
For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[6]	See Schedule 2 for manufacturing details

3. **Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[7]** YES*
*For manufacturing steps carried out in Australia. For overseas manufacturers evidence of satisfactory GMP compliance has been supplied.

3.1 **Periodicity of routine inspections (years):** NOT LESS THAN EVERY TWO YEARS

3.2 **Has the manufacture of this type of dosage form been inspected?** YES

3.3 **Do the facilities and operations conform to GMP as recommended by the World Health Organization?[7]** YES

4. **Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?** YES

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Certificate of Listed Product

Certifying authority:

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Name of authorised person:

Nikolina Aslimoska

Signature: Nikolina Aslimoska

Date: 24/12/2024

No. of Schedules attached to this Certificate: 02

Certificate No. 24/1592

Explanatory Notes

1. This certificate, is not issued under the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving
   for a single product only, since manufacturing arrangements for different dosage forms and strengths can vary.
2. Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or appended.
4. When applicable, append details of any restriction applied to the sale, distribution or administration of the product
5. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and labels and/or releases for supply a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.
6. This information can only be provided with the consent of the product licence holder or, in the case of non-registered
   has not agreed to inclusion of this information. It should be noted that information concerning the site of production is
7. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspec
   The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those inclu
   for Pharmaceutical Preparations, WHO Technical Report Series No 823, 1992. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee
   on Biological Standardization and are published in the WHO Technical Report Series.
8. Subject to any applicable conditions under Commonwealth, State or Territory legislation.

A

I, Viet-Anh Nguyen, an officer of the Australian Embassy, Hanoi, having been duly authorised by the Secretary of the Department of Foreign Affairs and Trade, **DO HEREBY CERTIFY** that the signature/seal/stamp Nikolina Aslimoska, Delegate Of The Secretary, appearing on the document/s attached hereto is the true signature/seal/stamp of Nikolina Aslimoska. In so certifying, neither I nor the Australian Embassy, Hanoi endorse, verify or make any statement as to the accuracy, truth, legality or otherwise of the contents of the document or the purposes for which the document may be used. Neither I nor the Australian Embassy, Hanoi accept liability for any loss, damage or injury arising out of the use of, or reliance on, the document or its contents. I provide no undertaking that I have read the contents of the document.

GIVEN under my Hand and the seal of the Australian Embassy, Hanoi the 3rd day of February, 2025.

AUSTRALIAN EMBASSY 011 HANOI

Viet-Anh Nguyen
Authentication Officer
Australian Embassy, Hanoi

is

n of this section indicates that the party concerned
duction site is changed, the licence has to be updated

e aegis of the country of manufacture.
or the Thirty-second Expert Committee on Specifications

Australian Government
Department of Health and Aged Care

BỘ NGOẠI GIAO NƯỚC CHXHCN VIỆT NAM
MINISTRY OF FOREIGN AFFAIRS OF THE S.R. OF VIETNAM

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia ..... Việt Nam .....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) ..... Nguyễn Việt Anh ..... ký
has been signed by

3. với chức danh ..... Nhân viên lãnh sự .....
acting in the capacity of

4. và con dấu của ..... Đại sứ quán Úc tại Hà nội .....
bears the seal/stamp of

.....

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại ..... Hà Nội ..... 6. ngày 05 / 02 / 2025
at *the (dd/mm/yyyy)*

7. Cơ quan cấp ..... Cục Lãnh sự .....
by

8. Số 0032060 /CLS
N°

Ký tên và đóng dấu
Signature and seal/stamp

Phó Trưởng phòng Hợp pháp hóa lãnh sự

Mai Ngọc Quỳnh

BỘ NGOẠI GIAO
CỤC LÃNH SỰ

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Therapeutic Goods Administration

Summary of the Australian regulatory controls over drug products for human use

24/1592

The Commonwealth *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods supplied in Australia or exported from Australia. Therapeutic goods are products used in the prevention, diagnosis, cure or alleviation of a disease, ailment, defect or injury and include those goods which are likely to be taken for therapeutic use because of the way they are presented. Therapeutic goods which have been approved by the Therapeutic Goods Administration are included in the Australian Register of Therapeutic Goods (ARTG), which is a computer database holding details of therapeutic goods supplied in, or exported from, Australia. Some therapeutic goods are subject to the Act but exempt from listing on the ARTG. There are three categories of medicinal products in the ARTG:

1. **Registered medicines approved for supply in Australia**

Registered medicines are assessed as having a higher level of risk. The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data. Registered medicines, including prescription and non-prescription medicines, must display an 'AUST R' number on the label as proof of registration. Once included in the ARTG, registered medicines, if identical as those supplied in Australia, may be exported without further regulation. The sponsor of the medicine may request the TGA to issue a Certificate of Pharmaceutical Product for these products.

2. **Listed medicines (including complementary medicines) approved for supply in Australia**

Listed medicines are usually considered to be low-risk, so the regulations allow for sponsors to 'self-assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment. They are unscheduled medicines with well-known low-risk ingredients, such as vitamin and mineral products. These are assessed by the TGA for quality and safety but not efficacy. It is a requirement under the Act that sponsors hold information to substantiate all of their product's claims. Listed medicines must display an 'AUST L' number on the label as proof of listing. Once listed in the ARTG, these goods, if identical as those supplied in Australia, may be exported without further regulation. The sponsor of the medicine may request the TGA to issue a Certificate of Pharmaceutical Product or a Certificate of Listed Product for these products.

Export Certificates

The TGA provides two types of export certificates for medicines, a Certificate of Pharmaceutical Product and a Certificate of Listed Product. While both certificates are based on principles of the WHO Scheme for export certification, only the Certificate of Pharmaceutical Product is formally issued under this scheme. The Certificate of Listed Product is a modified certificate provided for medicines listed for supply in Australia. These goods are required to comply with part 3-3 of the Act and are manufactured under GMP.

Standards

All therapeutic goods that are exported from, imported into or supplied in Australia must comply with internationally recognised standards that are of a comparable standard to those that apply to such goods in Australia.

Licensing of manufacturers

All Australian manufacturers hold a valid TGA issued manufacturing licence for each manufacturing site that is applicable to the manufacturing steps performed. All overseas manufacturers hold a valid TGA issued Good Manufacturing Practice (GMP) clearance for each manufacturing site that is applicable to the manufacturing steps performed.

This page is intended as a summary of the main features of the national regulatory scheme. Specific queries or requests for clarification should be directed to:

Exports, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606, Australia

Exports can be contacted directly via email at tga.exports@health.gov.au

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Schedule 1

FORMULATION

5-MTHF Biologically Active Folate
AUST L 445966

Ingredients	Quantity
ACTIVES:	
levomefolate calcium	460 microgram
Equiv. levomefolic acid	400 microgram
EXCIPIENTS:	
magnesium stearate	
titanium dioxide	
colloidal anhydrous silica	
Carnauba Wax	
microcrystalline cellulose	
hypromellose	
macrogol 400	
povidone	
croscarmellose sodium	

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Schedule 2

MANUFACTURERS

5-MTHF Biologically Active Folate
AUST L 445966

Manufacturers

Silliker Australia Pty Ltd
Unit C2 / 391 Park Road Regents Park Estate REGENTS PARK NSW 2143 Australia
Manufacturing Steps:
Testing microbial

Ferngrove Pharmaceuticals Australia Pty Ltd
5 Ferngrove Place SOUTH GRANVILLE NSW 2142 Australia
Manufacturing Steps:
Testing chemical and physical
Secondary packaging
Release for supply
Packaging and labelling
Manufacture of dosage form

Southern Cross Analytical Research Laboratory
Level 3 T Block and N Block Military Road Southern Cross University LISMORE NSW 2480 Australia
Manufacturing Steps:
Testing chemical and physical

Chem-Chrom Laboratories and Services
Unit 15 / 10-12 Montore Road Minto NSW 2566 Australia
Manufacturing Steps:
Testing chemical and physical

Australian Laboratory Services Pty Ltd
Unit 10 2-8 South Street RYDALMERE NSW 2116 Australia
Manufacturing Steps:
Testing chemical and physical

Symbio Laboratories PTY LTD
2 Sirius Road Lane Cove West NSW 2066 Australia
Manufacturing Steps:
Testing microbial

Naturalab Pty Ltd
Level 2 / 111 Stephens Road BOTANY NSW 2019 Australia
Manufacturing Steps:
Testing chemical and physical

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