



Bahagian Regulatori Farmasi Negara
National Pharmaceutical Regulatory Agency
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

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GMP Certificate No. 2522(a)/22

Our Ref. : KKM/NPRA.PKP/600-2/5 (99) Jld. 23
Date : 30 March 2022

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia confirms the following:

The Manufacturer : **ExcelVite Sdn. Bhd.**
Site Address : **Lot 56442, 7 1/2 Mile,
Jalan Ipoh / Chemor,
31200 Chemor,
Perak,
Malaysia.**

Has been inspected in accordance with Malaysian Control of Drugs and Cosmetics Regulations 1984 and Malaysian Drug Registration Guidance Document (DRGD).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **1-2 March 2022**¹, it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-Operation Scheme (PIC/S) GMP Guides.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than two years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts I and II.

The authenticity of this certificate may be verified with the issuing authority.

(DR. NORAIDA MOHAMAD ZAINOOR) RPh. 2289
Head of Centre for Compliance & Quality Control
National Pharmaceutical Regulatory Agency

¹ This certificate has been granted based on remote inspection due to COVID-19 pandemic.



Certified to ISO 9001: 2008
Cert. No. AR 2293



Member of
Pharmaceutical Inspection
Cooperation Scheme



Non Member Adherence to
Mutual Acceptance of
Data for GLP



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Part II

√ Human Medicinal Products

3. MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

3.2	Extraction of active substance from natural sources
	3.2.1 Extraction of substance from palm oil source (esterification) 3.2.6 Purification of extracted substance (molecular distillation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (blending and spray drying) 3.5.2 Primary packaging 3.5.3 Secondary packaging
3.6	Quality Control Testing
	3.6.1 Physical/chemical testing 3.6.2 Microbiological testing (non-sterility testing)

Active Substance(s):

Powder:

- 1) EVTeneSol™ Range of Products
- 2) EVNolMax™ Range of Products
- 3) EVNolMax™ (T) Range of Products
- 4) EVRol™ 80%, EVRol™ 50% and EVRol™ 25%
- 5) EVNolBev™ 15%

Liquid (oil based):

- 1) EVNol™ Range of Products
- 2) EVNol™ 50%C (N) / EVNol™ 50%C (L)
- 3) EVNolEgg™ 20% / EVNol™ 20% (V)
- 4) EVNol SupraBio™ 25%
- 5) EVNol SupraBio™ 20% (N)
- 6) EVNol SupraBio™ 20%
- 7) EVNol SupraBio™ 20% (P)
- 8) EVTene™ Range of Products
- 9) EVOlein™
- 10) EVPene™ Range of Products
- 11) EVSpectra™ 30/10, EVSpectra™ 20/5, EVSpectra™ 10/5, EVSpectra™ 16.5/3.2, EVSpectra™ 3/3 (V), EVSpectra™ 2/3 (V), EVSpectra™ 0.6/0.3, EVSpectra™ 0.2/0.1
- 12) Palm Oil Carotene Interim Product 5%
- 13) EVTene™ 3% (T) / EVTene Feed™ 3%

Any restrictions or clarifying remarks related to the scope of this certificate: -None-

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