

BAHAGIAN REGULATORI FARMASI NEGARA

National Pharmaceutical Regulatory Agency

KEMENTERIAN KESIHATAN MALAYSIA

Ministry of Health Malaysia

Lot 36, Jalan Prof. Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor, Malaysia

Tel: +603-78835400 https://www.npra.gov.my

GMP Certificate No. 3401(a)/24

Our Ref.

: KKM/NPRA.PKP/600-2/5 (| 1)

Date

: 20 February 2024

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 ½ 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 **16-17 January 2024**, 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 three 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.

(AIDA HARYATI ABDUL RAHIM) RPh. 3845

Head of Good Manufacturing Practice Section Centre for Compliance & Quality Control National Pharmaceutical Regulatory Agency







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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)		
		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)		

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Cert. No. QMS 00894







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Part II

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) EVNolTM 50%C (N) / EVNolTM 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) / EVTeneFeed™ 3%

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

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Mutual Acceptance of

Data for GLP