

## CERTIFICATE OF ANALYSIS

<b>Date: 1<sup>st</sup> Aug 2024</b>	<b>Certificate number: 39780</b>
<b>Product name: 5-MTHF Biologically Active Folate</b>	<b>Batch number: 36295</b>
<b>Product code: TB-LECA400, Ver #5</b>	<b>Sponsor: Vitopharm Biotech Pty.Ltd</b>
<b>Manufacturing date: 28<sup>th</sup> May 2024</b>	<b>Expiry date: 28<sup>th</sup> May 2027</b>
<b>Storage conditions: Store below 30°C, away from direct heat &amp; sunlight.</b>	<b>Dosage form: Tablet, film coated</b>
<b>Lab certificate number: J2024-1209 / 2024-1052 / S1547810-C-1[R00]</b>	<b>Analysis date: Refer to lab certificates</b>

Physical and Chemical Test	Specification	Results
Description	8 mm round white film coated tablet	Complies
Uniformity of weight (As per BP/TGO 101)	None >15%; NMT 2 >7.5%	Complies
Total weight	200 mg±7.5% (185.0-215.0) mg/tablet	205.0 mg/tablet
Disintegration (As per BP)	Not more than 30 minutes.	<14 minutes
<b>Assay of Active Ingredient</b>		
Levomefolate calcium 30 Equiv. Levomefolic acid	0.46 mg/tablet 0.40 mg/tablet (0.36-0.6) mg/tablet*	- 0.415 mg/tablet
<b>Heavy Metals Release Limits for Finished Products</b>		
Cadmium	NMT 5 ppm ^	Complies
Lead	NMT 5 ppm ^	Complies
Arsenic (Inorganic)	NMT 15 ppm ^	Complies
Mercury	NMT 2 ppm ^	Complies
<b>Microbiological Test (As per TGO 100 &amp; Microbial Rotational Test Program)</b>		
Total Aerobic Microbial Count	≤ 10 <sup>4</sup> CFU/g	<10 CFU/g
Total Yeast and Mould Count	≤ 10 <sup>2</sup> CFU/g	<10 CFU/g
Bile-tolerant Gram negative bacteria	≤ 10 <sup>2</sup> CFU/g	<10 CFU/g
Salmonella	Absent in 10g	Not detected/ 10g
Escherichia coli	Absent in 1g	Not detected/ 1g
Staphylococcus aureus	Absent in 1g	Not detected/ 1g

\* The first 3 batches of finished products will be assayed and then as part of a rotational testing program 1 batch in every 10th batch manufactured or annually, whichever comes first, will be tested thereafter.

^ Heavy Metals Release Limits are calculated based on maximum daily dose of 1 tablet. Heavy metals concentration of finish product will be quantified by input based on the heavy metal concentration in each raw material.

All batch documents have been reviewed and the above tests have been carried out.

APPROVED AND ISSUED BY:

Mengjiao Li  
Quality Assurance Officer



01-08-2024